Cleveland State Law Review

Volume 57 | Issue 3 Article

2009

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A "MOVING BAR" APPROACH TO ASSESSING THE ADMISSIBILITY OF EXPERT CAUSATION TESTIMONY

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I. INTRODUCTION: WHAT *VOSBURG V. PUTNEY* CAN TEACH US ABOUT THE MODERN LAW OF EXPERT EVIDENCE

Virtually every first year American law student learns the case of *Vosburg v. Putney*.[1] As one commentator has put it, "*Vosburg v. Putney* has, upon years of dedicated service in many capacities, achieved within the realm of torts a distinction it shares with a small circle of other Anglo-American cases . . . ."[2] It is hardly surprising that *Vosburg* has become perhaps one of the most celebrated tort cases in American law: Wrapped within its elegantly simple fact pattern[3] are fundamental questions of intent, comparative negligence, and proximate causation.[4]

What is arguably surprising, however, is that *Vosburg* has been taught exclusively as a "torts" case, with little to no attention having been paid to the case's profound lessons on the relationship between "substantive" tort law and the "procedural" law of expert evidence. After all, the *Vosburg* jury was not left unassisted in determining whether the defendant's "slight" kick to the shin of the plaintiff was the cause-in-fact of the plaintiff's debilitating bone injury. Rather, at trial the jury heard significant expert testimony on the causation-in-fact question. On the one hand, the plaintiff introduced the testimony of Doctors Joshua Bacon and Hugo Philler, the plaintiff's treating physicians. Each testified that, in their expert medical opinion, the "exciting cause of [the bone destruction] was the application of some force (a kick or a blow) to [the plaintiff's] leg."[5] Specifically, Dr. Philler testified that, although the plaintiff's "medical history indicated heightened susceptibility to infectious diseases," he "had spotted nothing to persuade him that

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[1] Vosburg v. Putney, 56 N.W. 480 (Wis. 1893) (holding that defendant, who lightly but intentionally kicked a fellow student on the shin, was fully liable for the unforeseeable bone destruction resulting from the kick). At Harvard Law School, *Vosburg* was the first case I was assigned to read in my first-year Torts class.

[2] *See* Zigurds L. Zile, Vosburg v. Putney: *A Centennial Story*, 1992 WIS. L. REV. 877, 988 (1992).

[3] The facts of *Vosburg* are as follows:

> The plaintiff was about 14 years of age, and the defendant about 11 years of age. On [February 20, 1889], they were sitting opposite to each other across an aisle in the high school of . . . Waukesha. The defendant reached across the aisle with his foot, and hit with his toe the shin of the right leg of the plaintiff. The touch was slight. The plaintiff did not feel it . . . . In a few moments he felt a violent pain in [his right shin], which caused him to cry out loudly. The next day he was sick and had to be helped to school. On the fourth day [after,] he was vomiting . . . . There was a slight discoloration of the skin entirely over the inner surface of the tibia an inch below the bend of the knee. . . . [O]n the 8th of March an operation was performed on the limb by making an incision, and a moderate amount of pus escaped. . . . On the sixth day after this, another incision was made to the bone, and it was found that destruction was going on in the bone, and so it has continued exfoliating pieces of bone. [The plaintiff] will never recover the use of the limb. There were black and blue spots on the shin bone, indicating that there had been a blow.

Vosburg v. Putney, 47 N.W. 99, 99 (Wis. 1890).

[4] *See, e.g.*, Robert Rabin, *Preface* Vosburg v. Putney *in Three-Part Disharmony*, 1992 WIS. L. REV. 863, 864-65 (1992) ("What better introduction to the subtleties of tort law?").

[5] Zile, *supra* note 2, at 959.

[the plaintiff] would have developed osteomyelitis whether or not force had been applied" to the plaintiff's leg.[6] Dr. Philler concluded that the plaintiff's bone "disease began as osteomyelitis . . . within the bone marrow" and that although "the infectious material traveled to the tibia from the inadequately treated and poorly healing wound above the knee" sustained in an earlier accident involving an axe, "'such disastrous results should [not] have occurred without a secondary traumatism.'"[7] On the other hand, the defendant introduced at least four medical experts in rebuttal, who collectively testified that although "[s]ome cause was necessary to localize osteomyelitis," bone growth "was the most common cause."[8]

It is hard to say definitively whether a relatively light kick to the shin *could have been*[9] the "exciting cause" of young Vosburg's "localized osteomyelitis" of the tibia. But, this is beside the point. Modern evidentiary standards do not allow the admission of a causation-in-fact expert whenever there is a non-zero possibility that the expert's opinion is correct. In other words, the question is not whether the expert has established a non-zero possibility of a causal connection between the defendant's act and the plaintiff's injury.[10] Rather, the relevant question is whether the testimony of the expert is sufficiently "reliable" to warrant admission to the jury.

The opinions of Drs. Bacon and Philler were based on the "germ or microbe theory of disease," which hypothesized that all bone inflammation and disease was caused by the presence of pus-forming germs that needed an "exciting cause" of some sort to grow and become harmful in the body.[11] At the turn of the twentieth century, germ theory was "still but grudgingly received by American medical science."[12] Moreover, neither Drs. Bacon nor Philler were able to cite to any studies

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[6] *Id.* at 960.

[7] *Id.*

[8] *Id.* at 961.

[9] The qualifying phrase "could be" sounds in terms of "general causation." *See, e.g.*, *In re* Hanford Nuclear Reservation Litig., 292 F.3d 1124, 1133 (9th Cir. 2002) (explaining that general causation refers to "whether the substance at issue had the capacity to cause the harm alleged, while 'individual causation' refers to whether a particular individual suffers from a particular ailment as a result of exposure to a substance").

[10] If an expert can reliability testify only to a possibility of a causal connection, then it will be excluded as failing the second prong, or "fit" requirement, of the Rule 702 analysis. *See, e.g.*, Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1398 (D. Or. 1996) ("[T]he plaintiffs in this litigation must prove not merely the possibility of a causal connection between breast implants and the alleged systemic disease, but the medical probability of a causal connection. Under this substantive standard, if an expert cannot state the causal connection in terms of probability or certainty, the expert's testimony must be excluded under the second prong of Rule 702."). Professor Berger has previously remarked on this phenomenon of incorporating sufficiency of the evidence standards directly into the admissibility inquiry. *See* Margaret A. Berger, *Upsetting the Balance Between Adverse Interests: The Impact of the Supreme Court's Trilogy on Expert Testimony in Toxic Tort Litigation*, 64 LAW & CONTEMP. PROBS. 289, 323-25 (2001) [hereinafter Berger, *Upsetting the Balance*].

[11] Zile, *supra* note 2, at 912. Doctors Bacon and Philler appeared to believe that virtually anything could be an "exciting cause"—for example, a physical blow, exposure to cold or dampness, malnutrition, or overexertion. *See id.* at 913.

[12] *Id.* at 912.

or experiments tending to show that a light blow could cause a rapid destruction of bone, even a bone left vulnerable by a latent bacterial infection. Indeed even today, the relationship between trauma and bacterial induced bone deterioration is not well known.[13]

All of this considered, it is likely that, if *Vosburg* occurred today, a trial court applying the so-called "*Dabuert* standard"—the prevailing standard for the admission of expert evidence in federal court and the courts of a majority of the states[14]—would find that the opinions of Drs. Bacon and Philler were not based upon a reliable methodology and, accordingly, would be inadmissible.[15]

Of course, the *Vosburg* case was litigated over one hundred years prior to the Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals*—and preceded even *Frye v. United States*[16] by over thirty years. Without strict admissibility standards for expert evidence yet in place, the Wisconsin Supreme Court offered a terse response to the defendant's challenge to the admissibility of the opinions of Drs. Bacon and Philler:

> The only remaining assignment of error is that the court erred in permitting medical witness to give their opinions as to what was the exciting cause of the injury to Andrew [Vosburg]. We think that it was a proper subject for expert testimony, and hence that the error is not well assigned.[17]

Indeed, earlier in the litigation, in an opinion reversing a verdict in favor of Vosburg on other grounds, the Wisconsin Supreme Court offered a similar view:

> It is a very strange and extraordinary case. The [kick] would seem to be very slight for so great and serious a consequence [as occurred]. And yet

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[13] *See* Raymond T. Morrissy & Darrel W. Haynes, *Acute Hematogenous Osteomyelitis: A Model With Trauma as an Etiology*, 9 J. OF PEDIATRIC ORTHOPAEDICS 447, 455 (1989).

[14] *See, e.g.*, Chief Justice Thomas J. Moyer & Stephen P. Anway, *Biotechnology and the Bar: A Response to the Growing Divide Between Science and the Legal Environment*, 22 BERKELEY TECH. L.J. 671, 715 (2007) (recognizing that "[m]ost state courts have adopted the *Daubert* standard to determine the admissibility of scientific evidence . . . .").

[15] *See generally* Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993). The Wisconsin Supreme Court recently noted that it has not yet adopted the *Daubert* standard (which governs in federal court) as the governing standard in its own state courts. *See* Conley Publ'g Group Ltd. v. Journal Commc'ns, Inc., 665 N.W.2d 879, 892-93 (Wis. 2003); *see also* Green v. Smith & Nephew AHP, Inc., 617 N.W.2d 881, 890-91 (Wis. Ct. App. 2000) (holding that "[u]nder Wisconsin law, scientific testimony is admissible if it is an aid to the jury or reliable enough to be probative," though explaining that "[a]n opinion for which there is no proper foundation . . . is not reliable enough to be probative" (internal quotation marks omitted)); *see also* Andrew R. Stolfi, *Why Illinois Should Abandon* Frye*'s General Acceptance Standard for the Admission of Novel Scientific Evidence*, 78 CHI.-KENT L. REV. 861, 898 n.225 (2003) (noting that forty-five states have codified the federal Rule 702 or its equivalent).

[16] Frye v. United States, 293 F. 1013 (D.C. Cir. 1923) (holding that expert evidence is admissible only if based on a methodology that has "gained general acceptance" in the relevant scientific community), *overruled in part by* Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993).

[17] Vosburg v. Putney, 56 N.W. 480, 480 (Wis. 1893).

> the plaintiff's limb might have been in just that condition when such a slight blow would excite and cause such a result, according to the medical testimony. That there is great uncertainty about the case cannot be denied. But perfect certainty is not required. It is sufficient that it is the opinion of the expert medical witnesses that such a [kick] might produce such a result under peculiar circumstances, and that the jury had a right to find . . . that it did.[18]

The premise of the passage above is that the reliability of an expert's opinion is not for the court to decide, even as a threshold matter. Though that premise was consistent with the then-prevailing law, it is radically inconsistent with the modern jurisprudence of expert evidence and, in particular, *Daubert*. And this leads to an important insight: If *Vosburg* were litigated today, there might well be no *Vosburg*. The causation proffers of Drs. Bacon and Philler would be deemed inadmissible, and the trial court would accordingly grant Putney's motion for summary judgment.[19]

A modern scholar might regard the jury's verdict in *Vosburg* as proof that the combination of "junk science" and a sympathetic plaintiff is a powerful elixir. Why then is *Vosburg* not viewed as a paradigmatic example of the importance of a court's gatekeeping role with respect to expert evidence? One answer, to be sure, is that the admissibility issue in *Vosburg* is an anomaly of history, a result of an anachronistic legal regime that gave juries *carte blanche* to distinguish good science from bad. But, the better answer is that the verdict in *Vosburg* is regarded as "right"—not so much because it represents a *factually correct* determination of what *actually caused* Vosburg's catastrophic injury, but rather because it represents a socially acceptable outcome between the parties: Putney acted as a social deviant and therefore has no real basis to complain about being held liable for Vosburg's injury. Because the outcome of the case is regarded as "right"—the term "rough justice" comes to mind—one scarcely pays attention to the fact that Vosburg's case rested on dubious expert opinions.

The lesson that might be drawn is this: The greater the perceived reprehensibility of the defendant's conduct, the less the legal system hesitates to allow the jury to speculate regarding causation-in-fact.[20] In the *Vosburg* case, despite a strong intuition that a light kick simply could not have caused such a seriously destructive bone injury, one is not all that uncomfortable with the jury's verdict—or, more accurately, the trial court's decision to allow the jury reach that verdict because (1) there was evidence that Putney's conduct was morally depraved—that is to say, devoid of any social benefit and ostensibly taken only to harass and annoy Vosburg;

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[18] *See* Vosburg v. Putney, 47 N.W. 99, 99 (Wis. 1890).

[19] *See* JoEllen Lind, *"Procedural Swift": Complex Litigation Reform, State Tort Law, and Democratic Values*, 37 AKRON L. REV. 717, 772-73 (2004) ("It has become commonplace for federal courts to conduct a 'Daubert hearing' to test the admissibility of plaintiffs' crucial expert opinions early on in litigation; when the evidence is ruled inadmissible . . . a successful defense motion for summary judgment typically follows.").

[20] *See* Robert Cooter, *Torts as the Union of Liberty and Efficiency: An Essay on Causation*, 63 CHI.-KENT L. REV. 523, 524 (1987). As Professor Cooter writes, "Causation in tort law is, thus, a way of describing the point where personal freedom runs out and responsibility to others begins . . . . Deciding issues of causation in tort law requires an appeal to substantive values like liberty and efficiency." *Id.*

and (2) there was at least a *non-zero* possibility that the Putney's unlawful act was the cause-in-fact of the Vosburg's injury.[21]

The jury's speculation, based only on dubious expert testimony, that Putney's kick caused Vosburg's injury does not draw objection because it is consistent with Professor Malone's classic observation that where the defendant has violated an "exacting" rule of law that rests on "time-honored moral considerations," he "will be held responsible for any harm that can be causally associated in any plausible way with his wrongdoing."[22] Malone observed that in such circumstances, "[t]he court . . . will seldom hesitate to allow the jury a free range of speculation on the cause issue at the expense of an intentional wrongdoer who is charged with having physically injured another person."[23] Moreover, to the extent that Putney's behavior served no ascertainable social utility,[24] allowing the jury to impose liability on Putney is consistent with legal economists' view of the causation-in-fact element.[25]

And, yet, *Vosburg* arguably is *inconsistent* with the current majority standard for the admissibility of expert evidence. Under that standard, a trial court would exclude the type of novel, speculative causation-in-fact testimony that Vosburg's experts proffered, which would ultimately lead to summary judgment being granted in favor of the defendant.[26]

This Article argues that the Supreme Court's decisions in *Daubert* and *Joiner* imply an approach to the reliability, and hence admissibility, of causation experts

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[21] *See* Christopher H. Schroeder, *Rights Against Risks*, 86 COLUM. L. REV. 495, 500 (1986) (recognizing that if there is a non-zero possibility that *A* can cause *B*, if *A* is sufficiently repeated, eventually it will in fact cause *B*). The more unlawful the defendant's conduct, the more we are willing to assume that such conduct is empty of any social benefit. Indeed, if there is a non-zero possibility that the defendant's conduct actually caused the plaintiff's injury, that conduct is per se Pareto inefficient unless there is no ascertainable social benefit to the defendant's conduct. One who is of the view that the goal of tort law is to promote social efficiency should conclude that, all other things equal, it is better to over- rather than under-deter conduct that serves no social benefit and that, accordingly, the causation-in-fact "burden" should be significantly relaxed in such circumstances.

[22] Wex S. Malone, *Ruminations on Cause-in-Fact*, 9 STAN. L. REV. 60, 72-73 (1956).

[23] *Id.* at 72-73.

[24] *See* RICHARD A. POSNER, TORT LAW: CASES AND ECONOMIC ANALYSIS 27 (1982) ("Perhaps [Vosburg] should have worn a shinguard. But . . . the costs of the shinguard must be compared with the cost to [Putney] of not kicking [Vosburg.] The latter cost was presumably low—even negative.").

[25] Cooter, *supra* note 20, 63 CHI.-KENT L. REV. at 540 ("In this tradition, if efficiency requires holding the defendant liable, he is said to have caused the accident, but not otherwise . . . . 'Cause' is reduced to 'efficiency' in the sense that the ascription of legal cause is wholly dependent upon the judgment of economic efficiency . . . . Saying the defendant caused the accident means . . . that [economic] efficiency requires holding him liable.").

[26] The *Daubert* standard, which has essentially been codified in Federal Rule of Evidence 702 as amended in 2000, has been adopted by approximately thirty states, although the "exact number is difficult to determine." Cara Gitlin, Note, *Expert Testimony on Child Sexual Abuse Accommodation Syndrome*, 26 QUINNIPIAC L. REV. 497, 503 n.45 (2008). For the sake of simplicity, for the remainder of this paper, I treat *Daubert* as setting forth the applicable analysis for expert admissibility.

that conflicts with the way in which courts traditionally had determined whether to allow the jury to speculate on uncertain causation-in-fact questions. Largely moving past the debate of whether *Daubert* and *Joiner* set the admissibility bar too high or low, the Article instead criticizes the decisions on the ground that they suggest that the height of the reliability bar is static and should not be adjusted depending upon the circumstances of the defendant's possibly injurious conduct. Under the "all-or-nothing" liability rule, the exclusion of a plaintiff's expert causation evidence will necessarily result in under-deterrence. Conversely, the admission of a plaintiff's questionable expert will necessarily expose a defendant to potential liability for harm that, from a probabilistic perspective, it did not cause. This Article thus critiques the static bar approach from a deterrence perspective and argues that the nature of the defendant's conduct should be a factor in a court's determination of whether a plaintiff's causation expert's proffer is sufficiently reliable to warrant admission at trial.

Part II reviews the Supreme Court's decision in *Daubert* and its subsequent decision in *General Electric Co. v. Joiner*.[27] By linking "evidentiary reliability" with scientific validity, the Court's opinions in those cases imply a "static bar approach" to admissibility.[28] Part III proposes that, instead of a static reliability bar, a "moving bar approach" allowing the court to adjust the height of the reliability bar in response to the defendant's possibly injurious conduct would be more consistent with tort law's traditional treatment of causation-in-fact and more likely to achieve economically efficient deterrence. Part IV discusses some paradigmatic cases in which a moving bar approach might alter admissibility outcomes. Part V offers and responds to several potential objections to the moving bar approach.

II. THE INTERSECTION OF SCIENCE AND LAW: THE *DAUBERT* AND *GENERAL ELECTRIC V. JOINER* DECISIONS

In this section, the author discusses the Supreme Court's seminal decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.* and its subsequent opinion in *General Electric v. Joiner*. The author argues that by linking admissibility with the concept of scientific validity, these decisions suggest that the degree of reliability that must be demonstrated of a causation expert's proffer is not case specific. Rather, the height of the reliability bar is "static."

A. Daubert v. Merrell Dow Pharmaceuticals, Inc.

Between 1957 and 1983, approximately thirty million pregnant women were prescribed Merrell Dow's drug Bendectin to relieve symptoms of morning sickness, including nausea and vomiting.[29] In the mid-1970s, there arose anecdotal-based

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[27] General Electric Co. v. Joiner, 522 U.S. 136 (1997).

[28] Perhaps the simplest way to explain what I mean by "static reliability threshold" is to imagine that any expert opinion is given a reliability score that is measured in terms of scientific validity. When the reliability threshold is static, the reliability score that is required of any expert remains the same from case to case, regardless of the underlying facts or the nature of the suit. Professor Imwinkelried has used the phrases "invariant reliability threshold" and "uniform, minimum reliability level" to describe this. Edward J. Imwinkelried, *The Relativity of Reliability*, 34 SETON HALL L. REV. 269, 269 (2003).

[29] Merrell Dow Pharms. v. Havner, 953 S.W.2d 706, 708 (Tex. 1997).

concerns of a link between Bendectin and birth defects. Although more than thirty scientific studies had failed to demonstrate any such link, and although the FDA never revoked its approval of Bendectin, a rash of products liability suits ensued against Merrell Dow. "In virtually all the Bendectin litigation, the central issue [had] been the scientific reliability of the expert testimony offered to establish causation."[30] It was against this backdrop that the Supreme Court rendered its decision in *Daubert v. Merrell Dow Pharmaceuticals*. Jason Daubert and Eric Schuller were born with serious birth defects. Each of their mothers had used Bendectin during her first trimester of each pregnancy. Jason, Eric, and their parents filed a products liability suit in federal court against Merrell Dow alleging that Bendectin had caused their birth defects.[31] "After extensive discovery, [Merrell Dow] moved for summary judgment, contending that Bendectin [did] not cause birth defects in humans and that [Daubert and Schuller were] unable to come forward with any admissible evidence that it [did]."[32] Merrell Dow's expert, a physician and credentialed epidemiologist named Dr. Steven Lamm, testified that over thirty studies had found Bendectin to pose no risk of birth defects and that no study had ever found Bendectin to be a human terotagen.[33]

Daubert and Schuller did not contest Merrell Dow's experts' "characterization of the published record regarding Bendectin. Instead, they responded . . . with the testimony of eight experts of their own, each of whom also possessed impressive credentials."[34] Based upon animal studies, chemical analyses, and re-analyses of previous human subject Bendectin studies, these experts had "concluded that Bendectin can cause birth defects."[35]

Over the plaintiffs' objections, the district court excluded their experts' proposed testimony, holding that the experts' opinions were based upon analyses that had not been published or peer reviewed, thus precluding their admission under Federal Rule of Evidence 702.[36] The Ninth Circuit affirmed on the same grounds.[37]

In a unanimous opinion, the Supreme Court vacated the decision below. The Court held that "[n]othing in the text of [Rule 702] establishes 'general acceptance' as an absolute prerequisite to admissibility."[38] Indeed, the Court explained that such a prerequisite "would be at odds with the 'liberal thrust' of the Federal Rules and

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[30] *Id.* The cost of defending the suits ultimately became so burdensome that Merrell Dow voluntarily withdrew Bendectin from the market in 1983. *Id.*

[31] *See* Daubert v. Merrell Dow Pharms., 509 U.S. 579, 582 (1993).

[32] *Id.*

[33] *Id.*

[34] *Id.* at 584.

[35] *Id.* at 583.

[36] *See* Daubert v. Merrell Dow Pharms., 727 F. Supp. 570, 576 (S.D. Cal. 1989).

[37] *See* Daubert v. Merrell Dow Pharms., 951 F.2d 1128, 1131 (9th Cir. 1991). The Ninth Circuit added that, because the plaintiffs' experts' testimony had been prepared "solely for litigation," it would be scrutinized especially heavily. *See id.*

[38] *See Daubert*, 509 U.S. at 587.

their 'general approach of relaxing the traditional barriers to 'opinion' testimony."[39] The Court held that Rule 702 requires only that "scientific testimony or evidence . . . [be] relevant [and] reliable."[40] Still, although the district court had erred in imposing a general acceptance prerequisite, the Court made it clear that district judges must continue to act as gate keepers to ensure that all "scientific testimony" be "derived by the scientific method."[41]

In articulating the contours of Rule 702's general reliability standard, the Court stated that the inquiry should be "a flexible one," and it set out a non-exhaustive list of non-dispositive indicia of reliability: (1) whether the expert's conclusion is generally falsifiable through empirical testing; (2) whether the studies upon which the expert's opinion is based have been subjected to peer review; (3) whether the testing upon which the expert's opinion is based has a low error rate; and (4) whether the expert's conclusions have received general acceptance within the relevant scientific community.[42]

Although *Daubert* superficially appeared to "relax the 'austere standard' of the older *Frye* rule,"[43] there was immediate disagreement amongst commentators about "whether [the opinion] st[ood] for a liberal standard of admissibility or a conservative one."[44] Fifteen years later, there is some indication that "*Daubert* has made it harder, not easier, to get scientific testimony admitted."[45] In hindsight, at least one element of the *Daubert* opinion portended this outcome: the Court's linkage of evidentiary reliability—the polestar for admissibility—with the concept of scientific validity. The Court stated that the "overarching subject" of the Rule 702 admissibility inquiry "is the scientific validity—and thus the evidentiary relevance and reliability—of the principles that underlie a proposed [expert] submission"[46] and that "[i]n a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*."[47]

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[39] *Id.* (quoting Beech Aircraft Corp. v. Rainey, 488 U.S. 153, 169 (1988)).

[40] *Id.* at 589.

[41] *Id.* at 590. "That the *Frye* test was displaced by the Rules of Evidence does not mean, however, that the Rules themselves place no limits on the admissibility of purportedly scientific evidence . . . . [T]he trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589.

[42] *See id.* at 591-94.

[43] Susan Haack, *Of Truth, in Science and in Law*, 73 BROOK. L. REV. 985, 990 (2008).

[44] David L. Faigman, Elise Porter & Michael J. Saks, *Check Your Crystal Ball at the Courthouse Door, Please: Exploring the Past, Understanding the Present, and Worrying About the Future of Scientific Evidence*, 15 CARDOZO L. REV. 1799, 1819 (1994).

[45] Haack, *supra* note 43, at 990; *see also* David L. Faigman et al., *How Good is Good Enough? Expert Evidence Under* Daubert *and* Kumho, 50 CASE W. RES. L. REV. 645, 656 (2000) ("[T]he move from *Frye* to *Daubert* . . . raised the height of the admissibility bar . . . in a more complex way than is often appreciated by courts or commentators.").

[46] *Daubert*, 509 U.S. at 594-95.

[47] *Id.* at 590 n.9 (emphasis in original); *see also* Robert J. Goodwin, *The Hidden Significance of* Kumho Tire Co. v. Carmichael*: A Compass for Problems of Definition and Procedure Created by* Daubert v. Merrell Dow Pharmaceuticals, Inc., 52 BAYLOR L. REV. 603, 612 (2000) ("Daubert equates 'evidentiary reliability' with 'scientific validity.'"). Although

Regardless of whether it was the Court's actual intent, the passages imply an attempt to "incorporate[] into law a scientific attitude toward selecting scientific testimony" [48] and a "move toward a 'more scientific approach to admissibility.'"[49] In Professor Feldman's view, "the *Daubert* Court adopted an approach to determining the admissibility of scientific opinion that reflects scientists' own approach to deciding which information to consider when deciding questions of scientific fact." [50]

B. General Electric v. Joiner

In the short time after the Supreme Court issued its *Daubert* opinion, it remained unclear how deep a change it would work into the law of expert evidence. At the same time, one commentator called *Daubert* "the most important case involving the admissibility of scientific evidence in seventy years."[51] One court took the view that "*Daubert* only prescribe[d] judicial intervention for expert testimony approaching the outer boundaries of traditional scientific and technological knowledge."[52] Professor Joseph Sanders might best have summed up the alternative available interpretations of *Daubert*: "From a narrow perspective, *Daubert* simply resolved a longstanding issue in the law of evidence by holding that the Federal Rules of Evidence superseded *Frye*. From a wider perspective, the opinion represents an attempt to define, or perhaps redefine, the relationship between science and the law."[53]

In 1997, the Supreme Court's opinion in *General Electric Co. v. Joiner*[54] began to resolve some of these debates, as well as determine the viability of *Daubert*'s putative "dichotomy between methodology and conclusions."[55]

Robert Joiner began working as an electrician for the city of Thomasville, Georgia in 1973. "This job required him to work with and around the city's

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the Court assured that it would be "unreasonable" to require that "the subject of [an expert's] scientific testimony must be 'known' to a certainty" in order to be admissible, this was only because "there are no certainties in science." *Daubert*, 509 U.S. at 590.

[48] Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1, 2 (1995).

[49] Brian Leiter, *The Epistemology of Admissibility: Why Even Good Philosophy of Science Would Not Make for Good Philosophy of Evidence*, 1997 BYU L. REV. 803, 804 (1997) (quoting Feldman, *supra* note 48, at 1-2).

[50] Feldman, *supra* note 48, at 2.

[51] David E. Bernstein, *The Admissibility of Scientific Evidence After* Daubert v. Merrell Dow Pharmaceuticals, Inc., 15 CARDOZO L. REV. 2139, 2139 (1994).

[52] Lappe v. Am. Honda Motor Co., 857 F. Supp. 222, 228 (N.D.N.Y. 1994) (stating that *Daubert* applied only in cases of "novel scientific evidence") (citing *Daubert*, 509 U.S. 579).

[53] Joseph Sanders, *Scientific Validity, Admissibility, and Mass Torts After* Daubert, 78 MINN. L. REV. 1387, 1440 (1994) ("By placing the concept of scientific validity at the center of admissibility decisions, *Daubert* invoked scientific understandings of what constitutes good and bad science.").

[54] General Electric Co. v. Joiner, 522 U.S. 136 (1997).

[55] D. Michael Risinger et al., *The* Daubert/Kumho *Implications of Observer Effects in Forensic Science: Hidden Problems of Expectation and Suggestion*, 90 CAL. L. REV. 1, 5 n.12 (2002).

electrical transformers, which used a mineral-oil-based dielectric fluid as a coolant. Joiner often had to stick his hands and arms into the fluid to make repairs," and the fluid would "sometimes splash onto him, occasionally getting into his eyes and mouth."[56] "In 1983, the city discovered that the fluid in some of the transformers was contaminated with polychlorinated biphenyls (PCBs),"[57] which by then had been "widely considered to be hazardous to human health" for nearly a decade.[58]

In 1991, at the age of 37, Joiner was diagnosed with small cell lung cancer.[59] Joiner filed a lawsuit against General Electric Co., alleging that (1) General Electric had manufactured the PCBs that Joiner consistently had come into contact with during his years as an electrician; and (2) such exposure had "promoted" his cancer, which, but for his exposure to the PCBs, "would not have developed for many years, if at all."[60] One of Joiner's experts, Dr. Arthur Frank, testified that

> [i]t [was] more likely than not, given Mr. Joiner's limited tobacco use, and also considering his second hand tobacco smoke exposure, and given his age at the onset of lung cancer, 37 years, that tobacco smoke served only as the initiator of the cancer and that some other agent served as the promoter of the initiated cells. It was the promotion of these initiated cells which caused Mr. Joiner to be harmed.[61]

Another one of his experts, Dr. Arnold Schecter, stated that Joiner's cancer "was causally linked to cigarette smoking and PCB exposure," including exposure to "dioxins and dibenzofurans and related chemicals which frequently are found together in transformer fluids."[62] Joiner's expert, Dr. Daniel Teitelbaum, likewise testified that Joiner's "lung cancer was caused by or contributed to in a significant degree by the materials with which he worked."[63]

General Electric challenged the admissibility of Joiner's experts' opinions that PCBs were capable of causing small cell lung cancer in humans, arguing *inter alia* that "there are no epidemiological studies which show that PCBs cause small cell lung cancer in humans" and that Joiner's experts' "reliance on [mice] studies" for their conclusions was unjustifiable.[64] The district court found General Electric's second argument persuasive, finding Joiner's experts' reliance on mice studies "flawed for several reasons. First, there are only two studies. Second, the studies

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[56] *Joiner*, 522 U.S. at 139.

[57] *Id.* In testing its electrical transformers in 1983, the city found that 19.2% of its transformers contained hazardous levels of PCBs. *See* Joiner v. Gen. Elec. Co., 864 F. Supp. 1310, 1312-13 (N.D. Ga. 1994).

[58] *Id.* ("Congress, with limited exceptions, banned the production and sale of PCBs in 1978.").

[59] *Id.* at 139.

[60] *Id.* at 139-140.

[61] *Joiner*, 864 F. Supp. at 1314.

[62] *Id.* at 1320-21.

[63] *Id.* at 1321.

[64] *Id.* at 1322-23.

obviously used massive doses of PCBs."[65] The court determined that Joiner's "experts erred in relying on the mice studies to opine that PCBs caused Joiner's lung cancer 'to a reasonable degree of medical certainty.'"[66] The court held that it "need not address whether the studies that Plaintiffs' experts rely upon were conducted in a scientific manner, for the studies simply do not support the experts' position that PCBs *more probably than not* promoted Joiner's lung cancer . . . . [T]he opinions of Plaintiffs' experts do not rise above 'subjective belief or unsupported speculation.'"[67] Because the exclusion of his experts left Joiner without any evidence of causation, the district court granted summary judgment in favor of General Electric.[68]

The Eleventh Circuit Court of Appeals reversed the decision below.[69] The court described *Daubert* as having "loosen[ed] the strictures of *Frye*" in order to "make it easier to present legitimate conflicting views of experts for the jury's consideration."[70] *Daubert* set forth a two-prong test. "Under the first prong, evidentiary reliability, the district court must examine the reasoning or methodology underlying the expert opinion," but the court must "be careful not to cross the line between deciding whether the expert's testimony is based on 'scientifically valid principles' and deciding upon the correctness of the expert's conclusions."[71] "Under the second prong, relevance, the district court must determine whether the methodology or reasoning underlying the expert opinion relates to the issue at hand, i.e., whether it assists the trier of fact in understanding the evidence or a fact at issue."[72]

Ostensibly applying plenary review, the court of appeals found that Joiner's experts had applied a sufficiently reliable methodology to withstand a Rule 702 attack:

> In this case, [Joiner's] experts discussed the studies of at least thirteen different researchers, and referred to several reports of the World Health Organization that address the question of whether PCBs cause cancer. [Joiner's] experts testified that many of these studies were conducted and analyzed to test specific hypotheses about the relationship between PCBs and cancer, that many have been published in reputable scientific journals, and that they were generated and tested using the scientific method. In ruling [Joiner's] expert['s] testimony inadmissible, however, it appears that the district court . . . accepted defendants' criticisms of the conclusions reached in those studies, stating that "the studies simply do not support the experts' position that PCBs *more probably than not*

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[65] *Id.* at 1323.

[66] *Id*. at 1324 (quoting Wells v. Ortho Pharm. Corp., 615 F. Supp 262, 295 (N.D. Ga. 1985).

[67] *Id.* at 1326.

[68] *See id*. at 1327.

[69] *See* Joiner v. Gen. Elec. Co., 78 F.3d 524, 534 (11th Cir. 1996).

[70] *Id.* at 530.

[71] *Id.*

[72] *Id.*

> promoted Joiner's lung cancer." As *Daubert* makes clear, the district court may not decide whether an expert's opinions are correct, but merely whether the bases supporting the conclusions are reliable.[73]

The Supreme Court reversed and remanded. The Court first held that admissibility decisions under Rule 702 are to be reviewed under an abuse of discretion standard.[74] The Court next held that "a proper application of the correct standard of review here indicates that the District Court did not abuse its discretion" in excluding Joiner's experts.[75] The Court rejected Joiner's argument that the district court "committed legal error" in passing upon the reliability of his experts' *conclusions* rather than merely their methodologies:

> [C]onclusions and methodology are not entirely distinct from one another. . . . [N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.[76]

As to whether the district court had abused its discretion in concluding that "the studies upon which [Joiner's] experts relied were not sufficient, whether individually or in combination, to support their conclusions that Joiner's exposure to PCB's contributed to his cancer," the Supreme Court held that it had not.[77] The Court described the mice studies as "seemingly far-removed" from the question of whether Joiner's PCB exposure could have caused his specific cancer.[78] The Court also agreed that the "four epidemiological studies" on which Joiner's experts relied did not purport to establish a causal connection between lung cancer and PCBs and "did not support the experts' conclusion that Joiner's exposure to PCBs caused his cancer."[79]

Justice Breyer concurred in the majority opinion, and Justice Stevens sharply dissented. Justice Breyer's concurrence emphasized that a trial court's gatekeeping duties "must be exercised with special care" in cases "when law and science intersect," such as in toxic torts cases.[80] Because "modern life," Justice Breyer stated, "depends upon the use of artificial or manufactured substances," trial courts' "*Daubert* gatekeeping function" helped to "assure that the powerful engine of tort liability . . . points toward the right substances and does not destroy the wrong ones."[81] Moreover, Justice Breyer concluded that "*Daubert*'s gatekeeping

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[73] *Id.* at 533 (citation omitted).

[74] *See* Gen. Elec. Co. v. Joiner, 522 U.S. 136, 142-43 (1997).

[75] *Id.* at 143.

[76] *Id.* at 146.

[77] *Id.* at 146-47.

[78] *Id.* at 144.

[79] *Id.* at 144, 145.

[80] *Id.* at 148 (Breyer, J., concurring).

[81] *Id.* at 148-49.

requirement . . . will help secure the basic objectives of the Federal Rules of Evidence; which are . . . the ascertainment of truth and the just determination of the proceedings."[82]

Justice Stevens' dissent agreed with the majority that the district court's decision should have been reviewed under the abuse of discretion standard[83] but took the view that the district court's "reliability ruling . . . arguably [was] not faithful to the statement in *Daubert* that 'the focus, of course, must be solely on the principles and methodology, not the conclusions that they generate.'"[84] Justice Stevens thought that Joiner's experts had employed "a 'weight of the evidence' methodology," which was not "intrinsically 'unscientific'" or "the sort of 'junk science' with which *Daubert* was concerned."[85] In fact, Justice Stevens pointed out, the Environmental Protection Agency "uses the same methodology to assess risks, albeit using a somewhat different threshold than that required in a trial."[86] All in all, "it would seem that an expert could reasonably have concluded that [the various human and animal studies in combination] raises an inference that PCBs promote lung cancer."[87]

Joiner "represent[ed] a marked amendment to the content of the reliability standard announced in Daubert."[88] As an initial matter, the Court rejected the dichotomy between methodology and conclusions, which supplemented *Daubert*'s teeth significantly. More fundamentally, the case involved a choice between two "quite different methodologies in determining issues of causation."[89] On the one hand, there is the methodology of "the theoretical scientist, whose mission is to search for enduring truths about the state of nature."[90] That is, the question for the theoretical scientist is "'does substance A cause disease B?'"[91] On the other hand is the methodology of what might be termed "practical scientists," such as those "who advise environmental and public health regulat[ions]," and whose "mission is to make predictions about how likely it is that substance A is causing disease B."[92] Such scientists *are* in the business of determining whether a causal connection is

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[82] *Id.* at 150.

[83] *Id.* at 150 (Stevens, J., dissenting in part).

[84] *Id.* at 152.

[85] *Id.* at 153.

[86] *Id.* at 153-54. Indeed, the Court explicitly approved of this method of analysis in the context of administrative rulemaking in *The Benzene Case* over a decade earlier. *See* Indus. Union Dep't v. API, 448 U.S. 607, 656 (1980) (plurality opinion) ("[S]o long as they are supported by a body of reputable scientific thought, [OSHA] is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection.").

[87] *Id.* at 154.

[88] Michael H. Gottesman, *From* Barefoot *to* Daubert *to* Joiner*: Triple Play or Double Error?*, 40 ARIZ. L. REV. 753, 766 (1998) [hereinafter Gottesman, *Triple Play*].

[89] *Id.*

[90] *Id.*

[91] *Id.* at 769.

[92] *Id.*

"likelier than not," and they utilize the "weight of the evidence" methodology to reach their conclusions.[93] Rather than searching for some inherent truth, these scientists engage in traditional cost-benefit calculus.[94]

As a matter of precedent, the Court's opinion in *Joiner* left open the possibility that it is not an abuse of discretion to *admit* the practical scientist's "weight of the evidence" methodology—and, indeed, might not have been an abuse of discretion to admit Joiner's expert evidence. However, the tone of the Court's opinion at least carried with it an implication that the weight of the evidence methodology is, as a matter of law, insufficiently reliable under Rule 702.[95] After all, it characterized the opinions of Joiner's experts as "connected to existing data only by [their] *ipse dixit*."[96] Moreover, the weight of the evidence approach is designed to allow a risk assessor to reach cost-benefit conclusions, rather than to "ascertain the truth" of whether the defendant's actions were causally connected to the plaintiff's injuries. The approach therefore does not fit comfortably with Justice Breyer's concurrence, which emphasized the "ascertainment of truth" as one of the two primary objectives of the Rules of Evidence.[97] This might be why lower courts post-*Joiner* have explicitly adopted the view that Rule 702 requires a much higher degree of scientific certainty than that required for *ex ante* regulatory action.[98]

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[93] *Id.*

[94] *Id.*

[95] *See* Harvey Brown, *Eight Gates for Expert Witnesses*, 36 HOUS. L. REV. 743, 845 (1999).

[96] *Gen. Elec. Co.*, 522 U.S. at 146.

[97] *Id.* at 150. It is interesting to compare Justice Breyer's concurrence and its emphasis on "ascertainment of truth" with *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984). In *Ferebee*, the D.C. Circuit stated that

> a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists. As long as the basic methodology employed to reach such a conclusion is sound, such as the use of tissue samples, standard tests, and patient examination, products liability law does not preclude recovery until a "statistically significant" number of people have been injured or until science has had the time and resources to complete sophisticated laboratory studies of the chemical. In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific certainty but legal sufficiency; if reasonable jurors *could* conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury, the fact that . . . science would require more evidence before conclusively considering the causation question resolved is irrelevant.

736 F.2d at 1535-36.

[98] *See, e.g.*, Hollander v. Sandoz Pharms. Corp., 289 F.3d 1193 (10th Cir. 2002) (affirming the district court's exclusion of the plaintiff's causation expert, who testified to a causal connection between plaintiff's use of the drug Parlodel—prescribed as, among other things, a lactation suppressant to postpartum women—and her intracerebral hemorrhage less than a week after she began using the drug). The Tenth Circuit stated that

> [the plaintiff's] evidence provided support for the FDA's decision to withdraw the indication for Parlodel as a postpartum lactation suppressant, as well as for the decisions of experienced clinicians that the apparent risks of Parlodel outweighed the limited benefits of prescribing the drug as a lactation suppressant. However, the

To the extent that *Joiner* ratified the reliability of the theoretical scientist's methodology and cast substantial, if not complete, doubt as to the reliability of the practical scientist's methodology, *Joiner* reinforced *Daubert*'s explicit linkage between "evidentiary reliability" and "scientific validity."

C. Linking Evidentiary Reliability to Scientific Validity: A Static Bar Approach to Admissibility

Professor Berger has argued that the "unstated message" of *Daubert* and *Joiner* is that "evidence that is inconclusive from a scientific perspective automatically fails to satisfy" Rule 702's reliability threshold and thus must be excluded. [99] In other words, the quality of the evidence that is required for a "reliable courtroom conclusion"—that is, an expert proffer that meets the Rule 702's "reliability threshold"—is the same as that which theoretical scientists would require before reaching a "scientifically valid" conclusion for non-litigation purposes. This effectively means that, under *Daubert* and *Joiner*'s evidentiary philosophy, "science and the law are answering the same question when asked to determine causation."[100]

One consequence of linking evidentiary reliability with scientific validity is that "a uniform standard of 'reliability' . . . will apply equally no matter what the issue being litigated . . . ."[101] Returning to the *Vosburg v. Putney* example, if a scientist is asked whether a schoolmate's kick caused damage to a young man's shin bone, he or she does not need to know whether the blow was malicious as opposed to an unintentional act. Yet, as a matter of substantive tort law, traditionally the causation requirement has been "loosened" in cases where the defendant's conduct was particularly reprehensible.[102] To the extent that the "reliability screen . . . presumes that the [causation] question is one of scientific 'fact' rather than a policy choice in the context of scientific uncertainty" is "insensitive" to policy concerns that classically underlie substantive tort law.[103] This might be called a "static bar approach" to admissibility.

> district court did not abuse its discretion in ruling that the . . . evidence did not satisfy the Daubert standard of reliability.

Id. at 1217; *see also* Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1201 (11th Cir. 2002) ("[The] risk-utility analysis involves a much lower standard than that which is demanded by a court of law. A regulatory agency such as the FDA may choose to err on the side of caution. Courts, however, are required by the *Daubert* trilogy to engage in an objective review of evidence to determine whether it has sufficient . . . basis to be considered reliable.").

[99] Berger, *Upsetting the Balance*, *supra* note 10, at 297, 299.

[100] *Id.* at 299.

[101] Gottesman, *Triple Play*, *supra* note 88, at 762.

[102] *See, e.g.*, Malone, *supra* note 22, at 72-73.

[103] Gottesman, *Triple Play*, *supra* note 88, at 762; *see also* Rochelle Cooper Dreyfuss, *Is Science a Special Case? The Admissibility of Scientific Evidence After* Daubert v. Merrell Dow, 73 TEX. L. REV. 1779, 1794-95 (1995) (criticizing *Daubert*'s underlying assumption "that law and science are aimed at the same thing—finding the truth. This assumption makes law sound rather lofty, but it oversimplifies the role of courts and distorts the purpose of the rules they apply. A more accurate view is that adjudication is intended to restore social harmony among parties in dispute; what adjudication seeks is repose . . . . For some cases that very well may mean creating a compensatory mechanism even in the absence of clear

Daubert's and *Joiner*'s mode of analysis—linking admissibility to scientific validity—defaults to the *status quo ante*. That is, in cases of scientific uncertainty, the presumption is that law—at least tort law—should not intervene. [104] As Judge Posner once put it, "law lags science."[105]

Scholars have debated whether a "lagging tort system" is preferable to a more reactive system. Specifically, a court in the latter system will allow the jury to decide a case despite strong scientific uncertainty as to whether there is a causal connection between the defendant's conduct and the plaintiff's injury. On the one hand, a tort system that restrains from imposing liability in the face of scientific uncertainty tends to reduce the problem of inefficient over-deterrence: There can be little doubt that the potential for tort liability negatively affects the incentives to engage in conduct such as the creation and marketing of new drugs, vaccines, or other products—conduct that is often socially beneficial on net, even when accompanied by risk of harm.[106] To the extent the tort system becomes overzealous in its regulation, through imposition of liability, of socially beneficial activities that *possibly*—but not certainly—create harmful side effects, it begins to exhibit the same flaws as the so-called Precautionary Principle.[107] Professor Sunstein has argued, "[a]

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scientific proof of cause and effect."); Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 365 (1999) ("Epidemiologists do not have to make decisions about who should financially bear a risk, or about how responsibility for ascertaining and reducing a risk should be allocated.").

[104] Anthony Z. Roisman, *Conflict Resolution in the Courts: The Role of Science*, 15 CARDOZO L. REV. 1945, 1950-51 (1994) ("[*Daubert*'s presumption is] that it is better not to have a legal resolution of a dispute than to have the dispute resolved incorrectly. . . . [and] that individual members of society are more appropriate to bear the risks of commerce than is society as a whole or those who profit from the activities that create the risk.").

[105] Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) ("Law lags science; it does not lead it."); *see also* Merrell Dow Pharm., Inc. v. Havner, 953 S.W.2d 706, 728 (Tex. 1997) ("[T]he law should not be hasty to impose liability when scientifically reliable evidence is unavailable.").

[106] *See* Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 311 (1985) (arguing that tort liability "is most certain to have regressive risk consequences when it delays the introduction of new technology that has already received administrative approval."). Huber's polemic is the whooping cough vaccine. The vaccine resulted in a net savings of 413 lives per year. However, approximately 25 children per year suffered an adverse reaction to the vaccine that resulted in serious, long-term brain damage. The vaccine thus "increases the risk of one particular form of injury a little, but drastically reduces the risk of another." *Id.* at 288. Nevertheless, due to "too much regulation in the courts," one of the leading producers of the vaccine bailed out of the market in 1984. *Id.*; *see also* Susan R. Poulter, *Science and Toxic Torts: Is There a Rational Solution to the Problem of Causation?*, 7 HIGH TECH. L.J. 189, 192-93 (1992) ("Erroneous plaintiffs' verdicts and the corresponding overcompensation and over-deterrence are not just academic concerns. The prospect of useful products being driven from the market or of economic resources being diverted from productive uses is real, as the cases of vaccines and Bendectin illustrate.").

[107] "The precautionary principle simply reflects the classic adage: Better safe than sorry. The principle suggests that government should take precautions to protect public health and the environment, even in the absence of clear evidence of harm and notwithstanding the costs of such action." Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH.

rational system of risk regulation certainly takes precautions. But, it does not adopt the Precautionary Principle."[108] Thus, there are valid arguments that a tort plaintiff should be required to come forward with causation evidence that meets the standard of "scientific validity." If such evidence does not exist, the defendant should not be exposed to tort liability. Otherwise, the defendant might be deterred from engaging in conduct that, on net, is socially beneficial.

Yet, a lagging tort system necessarily risks under-deterrence of "inefficient risk-taking."[109] At any given time, entire classes of plaintiffs will be foreclosed from receiving compensation because the science demonstrating a causal connection between their injuries and would-be defendants' actions is in its infancy stage, or simply not yet well enough developed to cross a reliability threshold that is based on scientific validity. Because there are legal impediments, such as statutes of limitations, that preclude would-be plaintiffs from waiting to bring their cases until the science has become more developed, a lagging tort system will necessarily fail to ensure that all actors will be forced to internalize the harms that their actions cause.[110] Moreover, in many circumstances the ethical and practical limitations of scientific testing will make it impossible for plaintiffs ever to come forward with causation evidence meeting a reliability threshold based on scientific validity.[111] In such cases, a putative defendant will escape any liability exposure even if it is agreed that there is a non-zero chance that its conduct has caused and continues to cause harm—the very definition of under-deterrence.

In modern society, scientific evidence often suggests a *possible* causal connection between a particular activity (ground water pollution, for example) and a particular harm (cancer); however, the evidence is not demonstrative of a *statistically or scientifically certain* causal connection. Thus, under an admissibility regime that demands such statistical or scientific certainty, some amount of under-deterrence is unavoidable. Yet, a return to a "let it all in" regime is both unwise—it might solve the under-deterrence problem but would create in its place an over-deterrence problem—and impractical given the burdens already being placed on the judicial system. Still, solving the under-deterrence problem is critical because, in many

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& LEE L. REV. 851, 851 (1996). The logical flaw of the Precautionary Principle is that "regulation will often cause more . . . harm than good." *Id.* at 860.

[108] Cass R. Sunstein, *The Paralyzing Principle*, REGULATION, Winter 2002-2003, at 37.

[109] David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849, 862 (1984).

[110] Although there has been very little, if any, study of *Daubert* from the perspective of law and economics, intuitively the *Daubert* standard must result in a failure to optimally deter possibly harmful conduct. *Cf.* Steve Gold, Note, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376, 397 (1984) ("Any system of all-or-nothing awards is economically inefficient in toxic torts cases."). After all, the *Daubert* standard is "all-or-nothing"—at least when administered in a tort regime that utilizes an "all-or-nothing" preponderance of the evidence approach to compensation—in the sense that a plaintiff's expert causation evidence will be excluded (effectively sinking the plaintiff's case) even where the state of the science gives one reason to at least suspect a causal connection between *A* and *B*.

[111] Clifford Fisher, *The Role of Causation in Science as Law and Proposed Changes in the Current Common Law Toxic Tort System*, 9 BUFF. ENVTL. L.J. 35, 63 (2001).

contexts, "false negatives are costlier than false positives."[112] A new, creative solution might be in order.

One possible solution is to use a method of "'public law' adjudication as a substitute for the system's traditional individualized process in order to resolve causal connection questions . . . ."[113] "[T]he central component of this . . . approach is the replacement of the preponderance rule by a standard of proportional liability," and "courts would impose liability and distribute compensation in proportion to the probability of causation assigned to the excess disease risk in the exposed population, regardless whether that probability fell above or below the fifty-percent threshold and despite the absence of individualized proof of the causal connection."[114] Under this system, a plaintiff would not be required to introduce scientific evidence demonstrating a causal connection between his or her injuries and the defendant's conduct. Rather, the plaintiff would only need to introduce evidence demonstrating that the defendant's conduct increased the *risk* of the plaintiff's injury.[115] The plaintiff's recovery would be limited to the extent of the increase. For example, if a plaintiff's expert could reliably testify to a thirty percent likelihood that the plaintiff's injuries were caused by the defendant's conduct, then the defendant would be liable for up to thirty percent of the plaintiff's injuries.[116]

A second potential solution is even more radical: A defendant's liability is determined by a finding of inadequate testing. This solution—which might be called "inadequate testing liability"—is based not so much on optimal deterrence as on "tort law's corrective justice rationale that liability is linked to moral responsibility."[117] Professor Berger, one of the leading proponents of this solution, argues "that if a defendant is negligent in discovering and disseminating substantial adverse information about its product . . . it should be liable for adverse health effects in those exposed, and plaintiffs should be relieved of proving general causation."[118] This argument is premised on the view that "[a] corporation should

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[112] *Id.* at 47.

[113] Rosenberg, *supra* note 109, at 859.

[114] *Id.*

[115] Daniel A. Farber, *Toxic Causation*, 71 MINN. L. REV. 1219, 1220-21 (1987) ("[I]f there was a thirty percent likelihood that the defendant caused the plaintiff's cancer, the plaintiff would receive thirty percent of his total damages.").

[116] Although the proportional liability proposal was not intended as a solution to the problem of expert evidence *admissibility*, some evidence scholars have suggested a version of proportional liability to deal with the problem of scientific uncertainty. *See* Feldman, *supra* note 48, at 45 ("Another option would be to split damages in half . . . in any case in which the plaintiff could establish strong uncertainty about causation, and the defendant could not eliminate it. [Such a change] would increase the incentive for the makers of potentially toxic substances to investigate the substances' causal powers more carefully before distributing them widely.").

[117] Margaret A. Berger, *Eliminating General Causation: Notes Towards a New Theory of Justice and Toxic Torts*, 97 COLUM. L. REV. 2117, 2119 (1997) [hereinafter Berger, *Eliminating General Causation*].

[118] *Id.* at 2147. There have been a few different iterations of the inadequate testing proposal. For example, one commentator has argued that, if the plaintiff can show that the defendant inadequately tested its product, there should be a rebuttable presumption that the

have no incentive to gamble that its product is probably safe or that proving causation will likely take twenty years."[119]

Both the proportional liability and inadequate testing liability proposals have serious limitations and provide, at best, an imperfect answer to the under-deterrence problem inherent in a Rule 702 regime that equates evidentiary admissibility with scientific validity. With respect to the proportional liability approach, its applicability to circumstances outside the mass exposure context is doubtful.[120] As Peter Huber points out, "[o]nly mass-exposure defendants can practicably be called to account for the risk—as distinguished from the harm—they create, and only in the mass-exposure context do the proportional liability rules and streamlined 'public law' procedures make any sense."[121] Huber might be overshooting a bit, but his point that "only mass producers can be required to pay accelerated compensation for risk created"[122] is well taken.

More broadly, the proportional liability rule depends "upon the existence of reliable, meaningful information" about the probability that there is a causal connection between the defendant's conduct and the plaintiff's injury.[123] It is therefore unclear whether the proportional liability rule would provide much assistance to plaintiffs in circumstances of "[s]trong uncertainty about general causation."[124] In such circumstances, proportional liability would, at best, result in compensatory outcomes that approximate best guesses at the likelihood of causal connections.[125] Under a proportional liability regime, therefore, the *Daubert* inquiry would simply shift to an examination of whether a plaintiff's (or a defendant's) expert's opinion regarding the statistical causal connection between *A* and *B* clears the reliability threshold.[126] Thus, although proportional liability is an elegant

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product caused the plaintiff's harm. *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 834 (1997).

[119] Berger, *Eliminating General Causation*, *supra* note 117, at 2147.

[120] Indeed, it is not obvious that Professor Rosenberg would argue for application of proportional liability outside of the mass exposure context. *See* Rosenberg, *supra* note 109, at 858 ("The preponderance rule may be adequate for the set of sporadic accident cases in which causal indeterminancy arises randomly and always signifies a substantial chance that the defendant in fact harmed no one.").

[121] Huber, *supra* note 106, at 315.

[122] *Id.*

[123] Feldman, *supra* note 48, at 39.

[124] *Id.* at 40.

[125] *See* David A. Fischer, *Proportional Liability: Statistical Evidence and the Probability Paradox*, 46 VAND. L. REV. 1201, 1221 n.51 (1993).

[126] *See* Gold, *supra* note 110, at 397-98 ("Rosenberg imagines a mystically precise probability that would determine the proportional recovery. His proposal would have plaintiffs pick their preferred probability, plead it, and prove it, while defendants could assert lower probabilities. The trouble is that it may be impossible rationally to choose any such value. Even a convincingly proven value would still be only an estimate; hence no *scientific* justification exists for setting the proportion equal to the reported value rather than at some other point in the reasonable range. Yet, under such a system, plaintiffs and defendants would likely end up bidding for duplicative and wasteful studies, jockeying for possession of the

solution to the problems caused by the "all-or-nothing, more probable than not" regime, it does not appear to be an adequate solution to the potential under-deterrence problems inherent in a Rule 702 regime that links reliability to scientific validity.[127]

Perhaps the most intractable problem with the proportional liability rule, however, is a practical one: it is unlikely to be adopted by courts or legislatures. Even the leading proponents of proportional liability would likely concede that an abandonment of the all-or-nothing, more probable than not rule is unlikely to derive from the judiciary, if for no other reason than inertia.[128] And legislatures seem unlikely to abandon the preponderance rule, if only because such a change would be politically unpopular with a culture that largely disdains the plaintiff's bar.

The inadequate testing liability proposal is likewise far from an ideal solution either. As an initial matter, it is even more radical than the proportional liability proposal because it disregards causation as an element entirely.[129] Like proportional liability, it seems unlikely that either courts or legislatures would enact such a reform, which quite literally would create a new category of tort: failure to test adequately.[130] Beyond this, however, imposing liability for inadequate testing might not do much to simplify matters for the jury or the court. There would remain the problem of determining whether the defendant in fact failed to test its product adequately. In some cases this determination might be easy—for example, when there is evidence that the defendant was willfully blind to known risks,[131]

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study with the highest (or lowest) reported probability estimate."); Farber, *supra* note 115, at 1227 ("[C]ausation of diseases like cancer is so poorly understood . . . . Many toxic substances are relatively novel, and, given the long latency periods associated with cancer, sufficient evidence concerning health effects is not likely to be available for the foreseeable future . . . . Epidemiological studies are . . . helpful but often inconclusive regarding the level of risk created by a toxic substance."); Charles Nesson, *Agent Orange Meets the Blue Bus: Factfinding at the Frontier of Knowledge*, 66 B.U. L. Rev. 521, 534 (1986) (noting that there is "little likelihood of firm conclusions" on scientific causation questions).

[127] Professor Feldman has referred to this as a "timing problem": "[M]ass exposure . . . suits . . . are put in motion and require resolution before there is sufficient scientific data to determine reliably the causal powers of the substances in question." Feldman, *supra* note 48, at 45-46.

[128] *See* Fischer, *supra* note 125, at 1226. As Professor Fischer notes, "The type of proportional liability that does the best overall job of providing compensation and achieving corrective justice is proportional risk recovery." *Id.* Yet, "this version of proportional liability represents the most significant departure from traditional tort principles," and "[t]herefore, courts and legislatures are least likely to adopt it." *Id.*

[129] Richard L. Cupp, Jr., *Believing in Products Liability: Reflections on* Daubert, *Doctrinal Evolution, and David Owen's Products Liability Law*, 40 U.C. DAVIS L. REV. 511, 524 (2006) ("[Inadequate testing liability] is a bold proposal, not an evolutionary baby step.").

[130] *See* Margaret Berger & Aaron D. Twerski, *Uncertainty and Informed Choice: Unmasking* Daubert, 104 MICH. L. REV. 257, 259 (2005) (arguing that courts should "recognize the right of [consumers] to informed choice about risks associated with the use of a [product], a right that does not require plaintiffs to prove that the toxic agent was the cause of the plaintiff's harm.").

[131] *See, e.g.*, Barrow v. Bristol-Myers Squibb Co., No. 96-689-CIV-ORL-19B, 1998 U.S. Dist. LEXIS 23187, at *204 (M.D. Fla. Oct. 29, 1998) ("MEC, the party in the superior

particularly risks that could have easily been discovered with modest further testing. But in other cases, it would be a complex question and there is little reason to believe that a jury will be able to assess accurately whether the defendant tested sufficiently, an inquiry that would require a complex analysis of the costs and benefits of more testing and increased deliberation on the part of the defendant.

In addition, creating liability for inadequate testing would likely "delay the availability of innovative, potentially beneficial products." [132] Thus, the inadequate testing proposal would solve one problem—under-deterrence—but potentially result in an equally (or even more) serious problem—over-deterrence.

Finally, the inadequate testing proposal would seemingly operate as a *sui generis* rule applicable only in products liability torts. It would have no application in other contexts in which causation experts make up the heart of a plaintiff's case.

However, the proportional liability approach, and perhaps even the inadequate testing approach, should not be disregarded as potentially valuable changes to American tort law.[133] In the next section, the author offers a more modest, yet potentially effective, solution to the under-deterrence problem that *Daubert* might cause: Rather than a static bar approach to admissibility, risk assessment principles should be integrated into the expert evidence inquiry. Under this type of approach to admissibility questions, the degree of reliability that a court would require of expert causation testimony in any given case would be adjusted according to whether principles of economic efficiency and social utility pushed in favor of placing either more or less of the burden of uncertainty on the plaintiff.[134]

The author's proposal is based on the assumptions that (1) courts are required to assess the reliability of proffered expert testimony before allowing its admission;[135]

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position to know of the defects in [its silicone breast implants] and the party with the superior economic capability to design and conduct tests to determine the safety of its product before offering it for sale, essentially turned a blind eye to the harms that could befall a person implanted with its [product]. MEC took an 'ostrich approach' to potential harms from its product so that it could contend, as it has done in this case, that it 'did not know' of such harms when complaints were made.").

[132] *See* Feldman, *supra* note 48, at 46. Perhaps in an attempt to temper this concern, Professors Berger and Twerski have seemed to suggest that dispensing with the traditional causation requirement might be restricted to what they call "lifestyle" products. *See* Berger & Twerski, *supra* note 130, at 289. *But see id.* at 287 n.148 (conceding that there is no clear line between "therapeutic" and "lifestyle" drugs).

[133] The proportional liability is particularly attractive as a matter of theory. *See* Farber, *supra* note 115, at 1240 ("[T]he general policies of tort law are advanced by allowing proportional recovery."); Steven Shavell, *Uncertainty Over Causation and the Determination of Civil Liability*, 28 J.L. & ECON. 587, 587 (1985) ("[L]iability in proportion to the probability of causation is superior to all other criteria and results in socially ideal behavior."). However, the chance that courts or legislatures will widely adopt a proportional liability rule seems sufficiently remote. More modest alternatives that attempt to serve similar ends must be explored.

[134] To the extent that the plaintiff has the burden of demonstrating the reliability of its expert, the burden of uncertainty is necessarily placed on the plaintiff. Adjusting the reliability bar up or down, however, will determine just how much uncertainty the plaintiff will be forced to bear.

[135] In other words, my proposal assumes the continued existence of a gate-keeping duty.

and (2) that tort claims will continue to be governed under the traditional "all-or-nothing, more probable than not" rule with the plaintiff bearing the burden of proving causation. The proposal is based on the idea that the most problematic aspect of *Daubert*'s mode of analysis is not that it sets the reliability bar too high or too low, but that it suggests that the bar should be set in the same place in every case.

III. A MOVING BAR APPROACH TO ASSESSING THE RELIABILITY OF EXPERT CAUSATION TESTIMONY

The previous section demonstrated that *Daubert* and *Joiner* collectively imply that a court's assessment of whether expert causation evidence is sufficiently reliable to be admitted ought not be influenced by case-specific tort policy considerations, such as deterrence. This Article refers to this as the "static bar" approach to admissibility. Under such an approach, a court is not permitted to adjust the height of the reliability bar—that is, accept a lesser (or demand a greater) degree of reliability of a causation expert's proffer—based upon case-specific policy considerations.

In this section, the author proposes an alternative approach to questions of admissibility that would affirmatively incorporate case-specific policy considerations into the court's analysis of whether a causation expert's proffer is sufficiently reliable to warrant admission. This approach is called a "moving bar" approach to admissibility. The author first argues that policy considerations historically influenced courts in deciding whether to allow juries to speculate on uncertain causation-in-fact questions and that this was justified on economic grounds. The author then argues that because of the outcome determinative role of admissibility decisions in modern litigation, policy considerations should similarly influence courts in their analysis of whether a causation expert is sufficiently reliable to warrant admission.

A. The Traditional Role of Policy in Helping to Resolve Uncertain Questions of Causation

There can be no doubt that tort law and the modern regulatory system have been treated as distinct legal vehicles serving distinct ends. One of the most pellucid examples of this is Judge Weinstein's opinion in the *Agent Orange*[136] case. Although Judge Weinstein recognized that there was sufficient evidence of Agent Orange's toxicity to justify *ex ante* regulation of the product, there was insufficient evidence to warrant *ex post* compensation via tort law:

> The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one. In the former, risk assessments may lead to control of a toxic substance even though the probability of harm to any individual is small and the studies necessary to assess the risk are incomplete; society as a whole is willing to pay the price as a matter of policy. In the latter, a far higher probability (greater than 50%) is required since the law believes it unfair to require an

[136] *In re* "Agent Orange" Prod. Liab. Litig., 597 F. Supp. 740 (E.D.N.Y. 1984).

> individual to pay for another's tragedy unless it is shown that it is more likely than not that he caused it.[137]

Nevertheless, there is substantial literature documenting the tort system's goal of, and role in, deterring harmful conduct *ex ante*.[138] To the extent that "tort law generates penalties . . . that give future actors a material incentive either to take precautions while acting or to avoid the activity altogether,"[139] the tort system's goals and effects largely overlap those of the regulatory system.[140]

Consistent with its regulatory-type role in influencing the economic incentives of private actors, tort law has been shaped in significant ways by policy considerations,[141] and courts' decisions traditionally have been imbued with, and animated by, broader policy concerns. As Professor Malone wrote more than fifty years ago, courts' decisions regarding causation-in-fact could largely be explained by "the mysterious relationship between policy and fact."[142] Professor Prosser similarly treated causation as a "thin shell[] into which a variety of policy judgments could be poured."[143] Contemporary law and economics scholars take the normative view that the function of all tort rules is to "bring about . . . the efficient . . . level of accidents and safety,"[144] which undoubtedly rings of policy.

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[137] *Id.* at 781.

[138] *See, e.g.*, John C. P. Goldberg, *Twentieth-Century Tort Theory*, 91 GEO. L.J. 513, 544-45 (2003) (describing views of "compensation-deterrence theorists").

[139] *Id.* at 544.

[140] *See* Peter L. Kahn, *Regulation and Simple Arithmetic: Shifting the Perspective on Tort Reform*, 72 N.C. L. REV. 1129, 1135 (1994) ("If there were no formal administrative regulation of health and safety, the tort system would nevertheless provide some control over health and safety decisions by private parties such as product manufacturers or service providers."); Rosenberg, *supra* note 109, at 926 (arguing that class actions in particular provide a "comprehensive, regulatory perspective"); Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 31 (1972) ("[T]he creation of private rights of action can also be a means of regulation.").

[141] *See, e.g.*, Welco Indus., Inc. v. Applied Cos., 617 N.E.2d 1129, 1133 (Ohio 1993) (stating that tort law "is guided largely by public policy considerations"); MORTON J. HORWITZ, THE TRANSFORMATION OF AMERICAN LAW, 1780-1860, at 99 (1977). For example, according to Professor Horwitz's "subsidy thesis," the shift from strict liability to negligence in American law in the nineteenth century was driven by the desire to promote economic growth. Professor Horwitz's subsidy thesis has been attacked on empirical grounds. *See, e.g.*, Gary T. Schwartz, *The Character of Early American Tort Law*, 36 UCLA L. REV. 641 (1989).

[142] Malone, *supra* note 22, at 60-61 ("At the close of the [nineteenth century,] courts used the term 'cause' indiscriminately to express either their conclusion as to 'what happened' or as a means of explaining what law 'ought to do about it.'"). Professor Malone phrased the problem in terms of a range of possibilities that the defendant's conduct was a cause-in-fact of the injury that might satisfy a court enough to send a case to the jury. "The point at which [a court] might be satisfied can be expressed in many ways, such as 'barely possible,' 'possible,' 'not unlikely,' 'as possible as not,' 'probable,' 'highly probable,' or 'virtually certain.'" *Id.* at 67.

[143] Benjamin C. Zipursky, *Legal Malpractice and the Structure of Negligence Law*, 67 FORDHAM L. REV. 649, 689 (1998).

[144] Posner, *supra* note 140, at 33.

That policy considerations drive "substantive tort law"—that is, liability rules—does not rest easily with the fact that, as has been argued above, the *Daubert*/*Joiner* mode of analysis of assessing the "reliability" of an expert proffer is bereft of policy considerations. To be sure, *Daubert*'s recognition of a trial judge's gatekeeping role was driven by various policy concerns.[145] But, to the extent that "reliability" is to be determined according to "scientific validity," a court's reliability assessment should not be affected by policy considerations unique to the case at hand. As Professor Gottesman puts it, *Daubert* treats reliability as a "question . . . of scientific 'fact' rather than a policy choice in the context of scientific uncertainty" resulting in "policy choices [being] ignored under the guise of administering a rule of evidence."[146]

Because admissibility decisions essentially operate as "summary judgment substitutes,"[147] it should be cause for concern that the *Daubert*/*Joiner* mode of analysis results in trial outcomes that might impede the achievement of substantive tort policies—namely the goal of optimal deterrence. Setting aside whether this raises concerns under the Rules Enabling Act[148]—a topic that is far beyond the scope of this Article—it arguably demonstrates that *Daubert* took a wrong turn somewhere along the line.

The mistake lies in the premise that the tort system is foremost concerned with pure "truth-seeking."[149] Although it might sound absurd to criticize such a premise—if for no other reason than Federal Rule of Evidence 102 provides that "[t]hese rules shall be construed to secure . . . promotion of growth and development

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[145] *See, e.g.*, Bobby Marzine Harges, *An Analysis of Expert Testimony in Louisiana State Courts After* State v. Foret *and* Independent Fire Insurance Company v. Sunbeam Corporation, 49 LOY. L. REV. 79, 79 (2003) ("The policy reason behind the *Daubert* decision was to exclude 'junk' science and experts who would testify to anything without any scientific basis."); *see also*, *Joiner*, 522 U.S. at 148-49 (Breyer, J., concurring) (asserting that the "*Daubert* gatekeeping function . . . help[s] assure that the powerful engine of tort liability . . . points toward the right substances and does not destroy the wrong ones.").

[146] Gottesman, *Triple Play*, *supra* note 88, at 762.

[147] Lind, *supra* note 19, at 772-74 ("Where liability . . . turns on the opinions of conflicting experts, summary judgment would normally be precluded as a defense option . . . . However, if the plaintiff's experts' opinions can be excluded, this removes a linchpin source the plaintiff can use to oppose summary judgment. . . . [M]any commentators conclude the outcome of a *Daubert* hearing determines the outcome of a case."). Professor Ronald Allen has called it "inevitable" that, under *Daubert*, courts will "largely make[] sufficiency holdings in the guise of admissibility holdings." Ronald J. Allen, *Expertise and the Supreme Court: What is the Problem?*, 34 SETON HALL L. REV. 1, 12 (2003); *see also* Dale A. Nance, *Reliability and the Admissibility of Experts*, 34 SETON HALL L. REV. 191, 216 (2003) (suggesting the same but pointing out that admissibility rulings are reviewed under an abuse of discretion standard, while pure sufficiency rulings are reviewed *de novo*).

[148] *See generally* Michael H. Gottesman, *Should Federal Evidence Rules Trump State Tort Policy? The Federalism Values* Daubert *Ignored*, 15 CARDOZO L. REV. 1837 (1994) [hereinafter Gottesman, *Federalism Values*].

[149] Michael J. Saks, *Merlin and Solomon: Lessons from the Law's Formative Encounters with Forensic Identification Science*, 49 HASTINGS L.J. 1069, 1131 (1998) ("Daubert's approach places so high a value on truth-seeking that it is willing to risk the episodic (and perhaps cumulative) loss of public confidence.").

of the law of evidence to the end that the truth may be ascertained"[150]—there are myriad examples of "procedural" rules (including the Rules of Evidence) that cannot be justified by such an "ascertainment of truth" principle,[151] and still other times evidence is excluded even though it advances the quest for "truth."[152] The most that can be said is that "discovery of truth is only one of the aims of adjudication under the Federal Rules [of Evidence]."[153]

Professor Nesson argues that "[t]he aim of the factfinding process is not to generate mathematically 'probable' verdicts, but rather to generate acceptable ones."[154] Further, he argues that "[a]cceptable verdicts and probable verdicts might appear to coincide, given that one obvious way to gain public acceptance is to search for truth. But the correlation between probability and acceptability is not exact: a probable verdict may not be acceptable, and an acceptable verdict may not be probable."[155] Professor Nesson's insights coincide with scholars' descriptive and normative arguments regarding the critical role that policy considerations play in how courts deal with questions of causation-in-fact.[156] Law and economics scholars

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[150] FED. R. EVID. 102.

[151] *See* Charles Nesson, *The Evidence or the Event? On Judicial Proof and the Acceptability of Verdicts*, 98 HARV. L. REV. 1357, 1369 (1985) ("Many rules are indeed explicable in terms of a truth-seeking rationale. But, on close inspection, some procedures that are rationalized as truth-seeking devices are better understood as means to promote public acceptance of verdicts."). One example that Professor Nesson gives is the hearsay exception for dying declarations. According to Nesson, "The traditional explanations for admitting these declarations focus on the necessity and reliability of the evidence. . . . Reliability is predicated on the idea that a person 'would be unwilling to go to his maker with a lie on his lips.'" *Id.* at 1374. But, argues Nesson, "the reliability of such evidence is obviously overstated. . . . The trial process thus embraces, rather than excludes, the possibly unreliable evidence." *Id.*

[152] *See id.* at 1376 (arguing that "the attorney-client privilege more often impedes than advances the search for truth . . . .").

[153] Brian Leiter, *The Epistemology of Admissibility: Why Even Good Philosophy of Science Would Not Make for Good Philosophy of Evidence*, 1997 BYU L. REV. 803, 816 (1997).

[154] Nesson, *supra* note 151, at 1359. Professor Allen has described the view that "the litigation process is largely designed to yield accurate results" as "naive realism to the max." Allen, *supra* note 147, at 4.

[155] Nesson, *supra* note 151, at 1378.

[156] *See* Richard Delgado, *Beyond* Sindell*: Relaxation of Cause-in-Fact Rules for Indeterminate Plaintiffs*, 70 CAL. L. REV. 881, 891 (1982) ("Malone, Green, Keeton, and Prosser purport to find a sliding-scale approach, in which courts apply the causation-in-fact requirement with decreasing stringency as the equities or public policies increasingly favor recovery."); *id.* ("On its face a simple, mechanical formula requiring only a finding of physical fact, the requirement of but-for causation is in reality a contextual, policy-sensitive instrument."); Malone, *supra* note 22, at 61, 72 ("[P]olicy may often be a factor when the issue of cause-in-fact is presented sharply for decision . . . . We can now ask: How great must be the affinity of causal likelihood between the defendant's wrong and the plaintiff's injury in order to justify the judge in submitting the cause issue to the jury? The answer is that the affinity must be sufficiently close in the opinion of the judge to bring into effective play the rule of law that would make the defendant's conduct wrongful."); Michael S. Moore, *Thomson's Preliminaries About Causation and Rights*, 63 CHI.-KENT L. REV. 497, 501 n.25 (1987) ("The

in particular have treated the question of causation-in-fact as presenting not a question of factual probability but instead a question of acceptability, with economic efficiency being the measure of acceptability: "In [the law and economics] tradition, if efficiency requires holding the defendant liable, he is said to have caused the accident, but not otherwise . . . . Landes and Posner are more explicit than others about this policy judgment . . . . Saying the defendant caused the accident means, in their view, that efficiency requires holding him liable."[157]

To the extent that the decision whether to admit a plaintiff's causation expert merges with the decision whether to allow the plaintiff to withstand summary judgment, it is easy to see how the admissibility inquiry carries with it enormous policy implications. In cases illustrating that where the plaintiff's ability to withstand summary judgment depends upon the admissibility of her causation expert, the "degree of 'reliability' that is imposed as a precondition to allowing the . . . experts to testify . . . is going to influence where, along the spectrum, the competing societal interests will be balanced."[158] As Professor Gottesman points out,

> [a] government that deems the encouragement of new products more important than the risk of leaving victims uncompensated might insist upon a high degree of scientific certainty (or at least probability) before allowing a case to proceed. On the other hand, a government that balances the policies differently and values compensation and deterrence over the societal benefits of risky substances might allow plaintiffs to recover on a showing that is less conclusive.[159]

Although Professor Gottesman is correct in finding that *Daubert*'s mode of analysis is flawed because it "presumes that the [causation] question is one of scientific 'fact' rather than a policy choice in the context of scientific uncertainty,"[160] Professor Gottesman fails to develop adequately how the expert admissibility analysis ought to be amended in order to deal with this.

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influence of Malone, Edgerton, and Green is quite evident in the law and economics literature on causation. Thus, Guido Calabresi concludes to his satisfaction that 'in the law cause in fact' . . . is in the end a functional concept designed to achieve human goals." (quoting Guido Calabresi, *Concerning Cause and the Law of Torts: An Essay for Harry Kalven, Jr.*, 43 U. CHI. L. REV. 69, 107 (1975))); Steven Shavell, *An Analysis of Causation and the Scope of Liability in the Law of Torts*, 9 J. LEGAL STUD. 463, 502 (1980) (arguing that causation should be defined in order to serve "well-specified social goals" and that "[q]uestions about causation are to an important extent resolved by resort to intuitions about the justness of applying a rule of liability.").

[157] Cooter, *supra* note 20, at 540.

[158] Gottesman, *Triple Play*, *supra* note 88, at 761. Theoretically there might be cases in which the admissibility of a defendant's causation expert might determine whether the defendant can withstand summary judgment. But these circumstances are likely exceedingly rare, and possibly non-existent.

[159] *Id.* at 761-62. It is important to emphasize the distinction between "allowing" a plaintiff to recover and "mandating" that a plaintiff recover. To say that a rule "allows" a plaintiff to recover is only to say that the rule allows the plaintiff to withstand summary judgment.

[160] *Id.* Professor Gottesman points out that "in both Daubert and Joiner, the available data . . . [were] suggestive of causation." *Id.* at 769.

B. Beyond a Static Bar Approach to Assessing Reliability

A modest—yet potentially important—change to the admissibility mode of analysis would be to move away from what the author earlier called a "static bar approach" and toward an approach that varies the height of the "reliability bar" on a case-by-case basis in response to substantive tort policy considerations.[161] This might be called a "moving bar approach." Unlike a static bar approach—which can impede the attainment of substantive tort goals, and in particular optimal deterrence—a moving bar approach would better enable Rule 702 to be instrumental to the attainment of those goals.

The premise of the moving bar approach is that, in cases involving causal uncertainty, decisions regarding the admissibility of expert causation testimony are functionally equivalent to determining whether to send a so-called "loss of chance" case to the jury.[162] Accordingly, the mode of analysis for an admissibility decision should roughly mirror the mode of analysis courts traditionally have employed in deciding whether a plaintiff can withstand summary judgment in a loss of chance case. "[I]n the general run of things tort law has quietly dealt with under determination and loss of a chance through the rough and ready application of policy-driven distinctions."[163] Under a moving bar approach to admissibility, the mode of analysis for admissibility decisions (at least when such decisions involve causation experts) would likewise deal with uncertainty through a "rough and ready" application of policy considerations. The proposal for a moving bar approach largely sidesteps the question whether—as one symposium has put it—the reliability bar is

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[161] Professor Paul Milich has previously argued for a moving bar approach, but he would move the bar on entirely different grounds. In Milich's view:

> [I]n deciding how much evidence of reliability a trial judge should require before admitting novel or controversial scientific evidence, the standard . . . should adjust to the nature and complexity of the scientific dispute in question . . . . [I]f the scientific disputes in a particular case are not too technical . . . the trial judge can be comfortable admitting such evidence upon a modest showing of scientific support and letting the jury hear and resolve the disputes. But if the scientific disputes concern highly technical or complicated issues that a jury will not comprehend, let alone master, the trial judge should require a strong showing of established scientific support before admitting the evidence.

Paul S. Milich, *Controversial Science in the Courtroom:* Daubert *and the Law's Hubris*, 43 EMORY L.J. 913, 925-26 (1994).

[162] *See* Lind, *supra* note 19, at 772. "Loss of chance" is sometimes referred to as an "indeterminate plaintiff problem." *See, e.g.*, *In re* "Agent Orange" Prods. Liab. Litig., 611 F. Supp. at 1408 ("Given the lack of scientific basis for general causation and the significant uncertainties involved in proof of individual causation—that is, the indeterminate plaintiff problem—it cannot now be established with any appropriate degree of probability that any individuals who suffer from the diseases listed in the PMC's plan incurred them as a result of Agent Orange exposure, or that these diseases are more likely than others to be causally related."). Loss of chance cases often occur in the context of toxic torts, but this is not always the case. *See generally, e.g.*, Malone, *supra* note 22 (discussing various paradigmatic loss of chance cases).

[163] Aaron Twerski & Anthony J. Sebok, *Liability Without Cause? Further Ruminations on Cause-in-Fact as Applied to Handgun Liability*, 32 CONN. L. REV. 1379, 1383 (2000).

"too high, too low, or just right."[164] The moving bar approach suggests that the answers are "it depends" and "maybe all of the above."

Under a moving bar approach, a trial court could use policy considerations as a "thumb on the scale" approach with the reliability bar being either lowered or raised only very slightly in response to the particular facts of the case. Or the moving bar approach could operate more like a full-on sliding scale, similar to how criminal courts' treat the Fourth Amendment's "reasonableness" standard.[165] Finally, the nature of the defendant's possibly injurious conduct might simply be treated as an additional factor of indeterminate weight in the *Daubert* analysis.[166]

Under either version of the moving bar approach, the trial judge would adjust the height of the reliability bar up or down depending on the circumstances of the defendant's possibly injurious conduct. On the one hand, if the defendant's conduct were particularly reprehensible, or possibly injurious conduct such that potential over-deterrence did not present a concern from the perspective of economic efficiency,[167] then the trial judge would lower the height of the reliability bar. On the other hand, if the defendant's conduct was not particularly reprehensible, or if economic efficiency counseled a greater concern with over-deterrence, the converse would be true. The important point is this: It would be permissible for a court to take into consideration the specific nature of the defendant's allegedly tortious conduct when deciding whether the testimony of the plaintiff's causation expert is sufficiently reliable to qualify for admission into evidence. This would harmonize the admissibility inquiry with what Professor Malone described as the way in which

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[164] This was the question posed by the 2003 Seton Hall Law Review Symposium.

[165] *See* Illinois v. Gates, 462 U.S. 213, 232 (1983) ("[P]robable cause is a fluid concept—turning on the assessment of probabilities in particular factual contexts—not readily, or even usefully, reduced to a neat set of legal rules."); *see also* Ronald J. Bacigal, *Putting the People Back into the Fourth Amendment*, 62 GEO. WASH. L. REV. 359, 395 (1994) (describing the "reasonableness" test under the Fourth Amendment as a "sliding scale" under which "reasonableness varie[s] according to the 'facts and circumstances of each case.'"); Ronald J. Bacigal, *The Fourth Amendment in Flux: The Rise and Fall of Probable Cause*, 1979 U. ILL. L.F. 763, 765 (1979) ("[T]he required degree of probable cause [is] a 'sliding scale' that fluctuates with the peculiar facts of each case.").

[166] The difficulty of integrating a subjective concept into an already amorphous test has been recognized in other contexts. For example, one commentator has argued that systematic investment asymmetries and their potential effect on optimal deterrence should be a factor in the class-certification calculus under Federal Rule of Civil Procedure 23(b)(3)'s superiority requirement, but concedes that the "approach is somewhat inexact." Randy J. Kozel, *Locating Investment Asymmetries and Optimal Deterrence in the Mass Tort Class Action*, 117 HARV. L. REV. 2665, 2681 (2004) ("Criticizing judicial consideration of litigation investment asymmetries simply for being inexact . . . is inconsistent with the oftentimes imprecise nature of modern class action practice.").

[167] Scholars have recognized that, if administrative costs are held constant, over-deterrence does not present a concern from an economic efficiency standpoint if the conduct at issue creates no efficiencies in the first place. *See, e.g.*, Thomas A. Lambert, *Tweaking Antitrust's Business Model*, 85 TEX. L. REV. 153, 191 (2006) (noting that "over-deterrence is not a concern in . . . cases" involving "practices that create no efficiencies, such as naked price-fixing").

courts traditionally had decided whether to allow the jury to speculate regarding causation-in-fact.[168]

IV. THE MOVING BAR APPROACH IN ACTION

In this part, the author offers a few paradigmatic cases in which a moving bar approach would mark a significant departure from a static bar approach: (1) cases involving intentional torts; (2) cases involving the violation of a criminal or regulatory statute that results in unintended injury to an unintended victim; and (3) cases involving possibly harmful products that provide objectively minimal benefits.

A. Intentional Torts

Under the Second Restatement of Torts, a tort is "intentional" when the actor "desires to cause consequences of his act, or . . . believes that the consequences are substantially certain to result from it."[169] This definition has been criticized as somewhat misleading,[170] and Professor Prosser has stated that intention under tort law "is not necessarily a hostile intent, or a desire to do any harm. Rather it is an intent to bring about a result that will invade the interests of another in a way that the law forbids."[171] Regardless, it is generally agreed that intentional torts are particularly reprehensible in that they violate rights that society has deemed "inalienable."[172] It is perhaps for this reason that law and economics scholars have argued that the optimal occurrence level of intentional torts is zero.[173] Likewise, "the

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[168] Implicit, then, in the moving bar approach is the idea that "reliability" under Rule 702 is a relative concept, a view that finds support in the Committee Notes to Rule 702. *See* FED. R. EVID. 702, Committee Notes (2000) (describing the "factors relevant in determining whether expert testimony is *sufficiently reliable* to be considered by the trier of fact" (emphasis added)). This is not necessarily a new idea. *See* Nance, *supra* note 147, at 194 ("Reliability is inherently relative to a particular decision context, and thus relative to the goal or purpose of decision."); Imwinkelried, *supra* note 28, at 269 ("The question is not whether the concept of reliability is a relative one. Rather, the issue is in which respects the concept is relative."). However, neither Professor Nance nor Professor Imwinkelried have previously suggested that the height of the reliability bar should move in response to the nature of the defendant's tortious conduct.

[169] RESTATEMENT (SECOND) OF TORTS § 8A (1965).

[170] *See* RICHARD A. EPSTEIN, CASES AND MATERIALS ON TORTS 9 (7th ed. 2000) (noting that §16 of the RESTATEMENT (SECOND) OF TORTS, which addresses battery, approves of the result in *Vosburg*, notwithstanding that the defendant in that case did not intend to cause serious harm to the plaintiff and could not have been substantially certain that such serious consequences would follow).

[171] PROSSER AND KEETON ON THE LAW OF TORTS 36 (W. Page Keeton et al. eds., 5th ed. 1984); *see also* Cleveland Park Club v. Perry, 165 A.2d 485 (D.C. Cir. 1960) ("[T]he intent controlling is the intent to complete the physical act [that is in and of itself unlawful] and not the intent to produce injurious consequences . . . .").

[172] *See, e.g.*, Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1124–27 (1972).

[173] WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF TORT LAW 153-56 (1987). Professor Coffee has argued that the law should never "price" intentional torts, but should always "prohibit" them. John C. Coffee, Jr., *Does "Unlawful" Mean "Criminal"?:*

danger of [damages awards] deterring socially valuable conduct . . . [is] minimized and other policies come to the fore, such as making sure that the damages award is an effective deterrent by resolving all doubts as to the plaintiff's actual damages in his favor . . . ."[174] Thus, as Professor Malone recognized, traditionally "courts 'seldom hesitate[d] to allow the jury a free range of speculation' on the question of cause-in-fact in [cases involving] intentional torts."[175] Accordingly, under a moving bar approach to admissibility, the trial court's ability to adjust the reliability bar downward in order to ensure that uncertainties toward causation are resolved in the plaintiff's favor should be at its maximum in cases involving what Judge Posner calls "real" intentional torts.[176]

Civil securities fraud claims regularly present difficult questions with respect to the causal connection between the defendant's conduct and the plaintiffs' damages, and expert testimony is virtually always required for the plaintiffs to obtain a damages award.[177] A good example of the causation problems that such cases can

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Reflections on the Disappearing Tort/Crime Distinction in American Law, 71 B.U. L. REV. 193, 239 (1991).

[174] Daniel P. Ryan, *Proposed Punitive Damages in Michigan: A Microeconomic Analysis of House Bill 5373*, 1998 DET. C.L. REV. 197, 207 (1998); *see also* William M. Landes & Richard A. Posner, *An Economic Theory of International Torts*, 1 INT'L REV. L. & ECON. 127, 136 (1981) (arguing that over-deterrence should be no concern with regards to intentional torts); Amelia J. Toy, *Statutory Punitive Damage Caps and the Profit Motive: An Economic Perspective*, 40 EMORY L.J. 303, 327 (1991) ("[S]ociety's concern with intentional [torts] is not that there will be less of the activity than desired (such is not possible), but that there will instead be more of the activity than desired . . . .").

[175] Twerski & Sebok, *supra* note 163, at 1381 (quoting Malone, *supra* note 22, at 60).

[176] Judge Posner describes "real" intentional torts as those that resemble common law crimes and do not involve a conflict between legitimate and productive activities but rather a coerced transfer of wealth to the defendant. *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 227 (5th ed. 1998). Other paradigmatic real intentional torts that routinely present uncertainties as to the extent of damages include theft of trade secrets and possibly "hard core" antitrust violations such as price fixing. *See, e.g.*, Jon Chally, Note, *The Law of Trade Secrets: Toward a More Efficient Approach*, 57 VAND. L. REV. 1269, 1295 n.113 (2004) ("Both in form and in substance misappropriation of trade secrets should be treated as a 'real' intentional tort. One who misappropriates a [trade] secret does not do so inadvertently while conducting otherwise socially advantageous behavior."); Robert H. Lande, *Are Antitrust "Treble" Damages Really Single Damages?*, 54 OHIO ST. L.J. 115, 116 (1993) (arguing that treble damages, to compensate for detection problems, are at least appropriate in cases of "per se, 'hard core'" offenses). The availability of treble damages is already a mechanism that compensates for the problems that are posed by uncertainties as to the extent of damages.

[177] *See* Behrens v. Wometco Enters., Inc., 118 F.R.D. 534, 542 (S.D. Fla. 1988) ("[P]roof of damages in a securities fraud case is always difficult and requires expert testimony . . . ."). Although this article has previously discussed experts testifying to causation, experts testifying to the *extent* of damages are in the same genre and therefore can be treated similarly under the moving bar approach. The primary difference between the two classes of experts is that the exclusion of the former will usually sink a plaintiff's case, whereas the exclusion of the latter will only reduce the plaintiff's potential recovery if liability is found.

present, and how the "moving bar" approach might make a difference, is *Kaufman v. Motorola, Inc.*[178]

Kaufman involved a class action brought by Motorola shareholders alleging that Motorola executives had both concealed the true nature of Motorola's inventory and had made misleading public statements regarding the inventory in order to artificially inflate the price of the stock.[179] The class alleged that Motorola executives sold off their shares at a profit after they publicly disclosed the problems with Motorola's inventory, resulting in a sharp stock decline.[180] In order to establish the extent of its damages, the class sought to admit the expert testimony of Dr. Gregg A. Jarrell, an economics scholar and former chief economist of the Securities and Exchange Commission. Dr. Jarrell was prepared to testify to the class's aggregate, as opposed to per share, damages, which he arrived at by "multiplying the alleged per share price differential by the aggregate number of shares that were 'damaged' by the alleged fraud."[181] In order to determine the aggregate number of shares that were "damaged," Dr. Jarrell used the so-called "proportional trading model."[182] According to Dr. Jarrell, the aggregate number of "damaged shares" could not be ascertained without the use of modeling because some of the shares purchased between the time of the fraudulent misstatements and the discovery thereof would have been purchased by short traders and other specialists not included in the plaintiff class.[183]

Motorola challenged Dr. Jarrell's proposed testimony on the ground that the proportional trading model was not sufficiently reliable under *Daubert*, and the trial court agreed.[184] Though stating that "[t]here is no question that Dr. Jarrell is a highly qualified economist," and that his "expertise was . . . clearly demonstrated to the court by his cogent explanation of the proportional trading model and its application to the facts of this case,"[185] the court nevertheless determined that the model failed *Daubert*:

> At first blush, the conclusion that the proportional trading model does not pass *Daubert* muster may appear to implicate the "flat earth" theory, under which one could assume that the first person to conclude that the world was round would have been considered heretically unscientific. The difference, of course, is that the "round earth" theory was subject to testing, and proven correct. Perhaps without such proof, the first person to conclude that the world was round would not have been allowed to so

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[178] Kaufman v. Motorola, Inc., No. 95 C 1069, 2000 U.S. Dist. LEXIS 14627 (N.D. Ill. Sept. 21, 2000).

[179] *Id.* at *4.

[180] *Id.*

[181] *Id.* at *3.

[182] *Id.*

[183] *Id.* at *4.

[184] *Id.* at *2-*3, *6-*7.

[185] *Id.* at *4-*5.

> testify before a jury if *Daubert* had been the law of what ever land that person lived in.
>
> In the instant case, Dr. Jarrell testified that there was no way to actually test the reliability of the proportional trading model. Whether this is correct or not, in absence of such testing and in absence of any acceptance by the professional economists of the theory, it simply does not pass *Daubert* muster.[186]

The court's language makes its *Daubert* conclusion appear simple and virtually ineluctable. However, the admissibility of statistical models for use in calculating aggregate damages in securities fraud cases was, and still is, a "hot button issue," and several courts have allowed the use of such modeling to estimate aggregate class damages.[187] The proportional trading model was not remotely archetypal "junk science," and yet the trial court's analysis suggests that it viewed the admissibility question as a rather easy one.

The *Kaufman* court's analysis is typical of the static bar approach because there is not a hint of substantive tort policy considerations in the court's analysis. The outcome might have been different had a moving bar approach been employed: A jury finding of fraud was a prerequisite to the imposition of compensatory damages, and the optimal occurrence rate of such securities fraud is arguably zero.[188] Thus, concerns with potential over-deterrence should have been either reduced or non-existent.[189] Moreover, although deeming Dr. Jarrell inadmissible did not preclude either liability or a damage award, it likely had a significant effect on the extent of

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[186] *Id.* at *6-*7.

[187] *See* Richard Bemporad & I. Scott Bieler, *Use of Experts in Securities Litigation*, 1386 PLI/Corp 645 (2003) (collecting cases).

[188] *See, e.g.*, Paul G. Mohoney, *Precaution Costs and the Law of Fraud in Impersonal Markets*, 78 VA. L. REV. 623, 647 (1992).

[189] Whether private 10b-5 actions might pose over-deterrence risks is currently a matter of scholarly debate and is beyond the scope of this paper. *See, e.g.*, Amanda M. Rose, *Reforming Securities Litigation Reform: Restructuring the Relationship Between Public and Private Enforcement of Rule 10b-5*, 108 COLUM. L. REV. 1301 (2008) (arguing that the threat of 10b-5 liability might overdeter issuers, who face strict liability for the frauds of their agents). More broadly, excessive corporate liability for the actions of rogue employees might result in the corporation adopting socially inefficient precautionary measures, such as preventative monitoring of employees. *See* Coffee, *supra* note 173, at 196. In addition, one could argue that the degree to which an actor is exposed to potential securities fraud penalties has an inverse relationship to the actor's willingness to provide even accurate securities-related information to the public. The moving bar approach would, of course, allow a trial court to take all of these things into consideration. As with many securities fraud cases, however, the conduct at issue in *Kaufman* involved both scienter and the highest echelons of Motorola's management. *See generally* Kaufman v. Motorola, Inc., Fed. Sec. L. Rep. (CCH) P90, 481 (N.D. Ill. April 16, 1999). Both factors diminish any over-deterrence concern. *See* Coffee, *supra* note 173, at 230 (arguing that where criminal behavior occurs within a corporation's senior levels, "then society should use penalties designed to prohibit, not price," because "we are again confronting behavior that lacks social utility, not the question how heavily to tax the corporation in order to induce monitoring.").

the damages that Motorola would be forced to pay if found liable.[190] For all of these reasons, a moving bar approach might have counseled the trial court to relax its demands on Dr. Jarrell, and it might have tipped the balance in the plaintiff's favor.

B. Cases Involving Knowing Violations of Criminal or Regulatory Provisions that Possibly have Resulted in Unintended Injuries to Unintended Victims

Cases involving intentional wrongdoing arguably present reduced or non-existent concerns with over-deterrence. Under a moving bar approach, in such a case a trial court might lower the reliability bar for a plaintiff's expert's proffer on causation. Under the prevailing static bar approach, however, the fact that the defendant's potentially injurious conduct involved a knowing violation of a criminal statute or regulatory provision is irrelevant to the reliability analysis.

Knowing and intentional violations of a discrete criminal statute or regulatory provision thus provide another useful context in which to examine the difference between the static bar and moving bar approaches.[191] Although such conduct often involves *intentional* harm, in many cases the causation question is with respect to unintentional harm to unintended victims.[192] Consider the case *Dellinger v. Pfizer Inc.*[193] Charles Dellinger underwent back surgery in 1994, and then again in 1996.[194] After the second surgery, he complained to his physician that he was experiencing extreme pain. His physician "told [him] about a new drug for pain management which had come highly recommended."[195] The drug was Neurontin, an FDA approved drug for the treatment of epilepsy. On September 19, 1996, Dellinger's physician prescribed Neurontin for the treatment of his pain, a use that was "off-label."[196]

Dellinger took Neurontin for the next eight months, at which point his physician "took him off [the drug] because the medicine did not appear to be helping [Dellinger's] pain."[197] Dellinger was placed on another prescription drug, doxepin. However, at the end of July 1997, Dellinger's physician discontinued the doxepin

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[190] Without Dr. Jarrell's testimony, the jury could only have been asked to find the amount of "per share" damages. Class members would then have to file individual compensation claims after the fact. Of course, it is unlikely that every class member would ultimately file such a claim, either because of lack of knowledge or transaction costs. Thus, the inadmissibility of Dr. Jarrell's testimony almost certainly reduced Motorola's exposure. That is, the court's admissibility decision gave Motorola a better chance of getting away with its alleged fraud more cheaply.

[191] Such violations are distinct from negligence per se, which does not require a showing of specific intent.

[192] Criminal dumping of chemical or other pollutants into a river or other water source is a typical example.

[193] Dellinger v. Pfizer Inc., No. 5:03CV95, 2006 U.S. Dist. LEXIS 96355 (W.D.N.C. July 19, 2006).

[194] *Id.* at *2.

[195] *Id.*

[196] *Id.* at *3.

[197] *Id.* at *4.

and re-prescribed Neurontin because Dellinger's pain was worse. On August 27, 1997, Dellinger was also prescribed Duract as an additional pain medication, and in late November 1997, he was also prescribed Prozac to counteract depression.[198]

In early 1998, Dellinger "began to experience severe lethargy, weakness, malaise, nausea and a metallic taste in his mouth."[199] On March 18, 1998, Dellinger was admitted to the Frye Regional Medical Center in Hickory, North Carolina, where he was diagnosed with pneumonia. Dellinger's medical records were "unclear" as to whether he also had pancreatitis.[200] "At the time . . . [Dellinger] was taking Neurontin, Prozac, Soma, Vicodin, and Elavil."[201] Doctors took him off all of his medication when he was admitted.[202] The next day, Dellinger was placed in the Intensive Care Unit ("ICU") and the following day he was placed on a ventilator; Dellinger remained on life support for the next two weeks.[203]

While Dellinger was in the ICU, his wife was "approached by Dr. Matt Brown . . . who advised her that she should question the use of Neurontin by her husband . . . ."[204] On April 7th, Dellinger improved and was discharged from the ICU. He was ultimately discharged from the hospital on April 23rd and discharged from his rehabilitation facility on April 28th.[205]

Upon his discharge from the rehabilitation facility, Dellinger refused to continue taking Neurontin, though he continued to take Vicodin, Prozac, and Elavil.[206] Although his health gradually improved, it would be over a year before Dellinger was "able to feed, bathe, and care for himself."[207]

In 2003, Dellinger's wife learned of reports that Pfizer and Parke-Davis, a division of Pfizer's subsidiary Warner-Lambert, "had developed a well-designed and extensive scheme to promote Neurontin as an 'off-label' drug."[208] The scheme

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[198] *Id.* Dellinger's physician discontinued the Duract in November 1997 because it caused Dellinger bouts of diarrhea. *Id.* at *4 n.5.

[199] *Id.* at *5.

[200] *Id.*

[201] *Id.*

[202] *Id.*

[203] *Id.*

[204] *Id.* at *5-*6.

[205] *Id. at* *6.

[206] *Id.* at *6-*7.

[207] *Id.* at *7.

[208] *Id.* In 2004, Pfizer "agreed to pay [the government] more than $430 million to resolve criminal charges and civil liabilities in connection with the promotion and marketing of Neurontin," and Warner-Lambert "plead guilty to two counts of violating the [Food, Drug, and Cosmetics Act]" and paid a criminal fine of $240 million. Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 FOOD & DRUG L.J. 1, 9 (2005). When Warner-Lambert's criminal plea was announced, the Department of Justice described the company's scheme as a "widespread, coordinated national effort to implement an off-label marketing plan" and stated that the company

included the hiring of "medical liaisons" who were "trained to use knowingly false information about Neurontin's 'off-label' uses when speaking with doctors and were told to lie about their credentials."[209] Moreover, the liaisons "engaged in repetitive distribution of non-scientific, anecdotal data designed to convince physicians that 'off-label' uses of Neurontin were safe and effective."[210]

Dellinger subsequently sued Pfizer and Parke-Davis. Dellinger claimed (1) that he would not have been prescribed Neurontin but for this illegal promotion of the drug as a pain medication, and (2) that Neurontin caused the illness that resulted in his being hospitalized for months and debilitated for over a year.[211] The defendants moved, *inter alia*, to exclude under *Daubert* the testimony of Dellinger's expert that Neurontin was the cause of his injuries.[212]

Dellinger's causation expert was Christopher Keeys, a clinical pharmacist with a degree in pharmacy.[213] Dr. Keeys proposed "to testify that [Neurontin] was 'probably the offending agent, and in the absence of medical etiologies, [the] cause of [Dellinger's] acute pancreatitis and subsequent complications . . . including [his] respiratory illness.'"[214]

The trial court deemed Keeys' testimony inadmissible. Although the court deemed Keeys unqualified to speak to the question of causation because he lacked a degree in pharmacology, the court alternatively determined that the substance of Keeys' opinion was not reliable "based upon the factors set out in *Daubert*,"[215] thus implying that Keeys' opinion would have been inadmissible even if he had been a pharmacologist.

Keeys had based his opinion on "product labels and data available from the FDA's adverse drug reaction reporting system . . . , published biomedical literature related to drugs associated with acute pancreatitis, product inserts and additional data regarding unpublished reports of acute pancreatitis, and a lack of positive re-challenge with reinstated medications in [Dellinger]."[216] The trial court found

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> decided not to seek FDA approval for any of the [off-label] uses because it was concerned that approval for any of the non-epilepsy uses would allow generic competitors of Neurontin, which was expected to go off-patent soon, to compete with a "son of Neurontin" drug that Warner-Lambert hoped to have approved by the FDA for both epilepsy and non-epilepsy uses.

Department of Justice Release, *Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion*, (May 13, 2004) *available at* www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm (noting that Warner-Lambert "aggressively" promoted Neurontin for, *inter alia*, "the treatment of . . . various pain disorders.").

[209] *Dellinger*, 2006 U.S. Dist. LEXIS 96355, at *8.

[210] *Id.*

[211] *Id.* at *9-*10.

[212] *Id.* at *25.

[213] *Id.* at *25-*26.

[214] *Id.* at *26 (quoting Plaintiff's Exhibit F).

[215] *Id.* at *28.

[216] *Id.* at *29. The "lack of positive re-challenge" referred to the fact that Dellinger's health had improved after he ceased taking Neurontin. This allowed Keeys to "rule in"

Keeys' opinion failed *Daubert*'s test for reliability. The court held that the adverse event reports had not been peer-reviewed and "fail[ed] to test a causal hypothesis."[217] As for Neurontin's labeling and package insert, which listed pancreatitis as a potential side effect, the court held that these were merely "regulatory document[s] that [were] generated from science *and* a collaboration of the industry with the FDA."[218] Because "Keeys' opinion regarding the temporal relationship between [Dellinger] taking Neurontin and becoming ill was never tested independently or by objective sources," the court held that his opinion that "Neurontin causes pancreatitis [or pneumonia was] not supported by medical or scientific literature."[219]

By the time that the *Dellinger* court ruled on the defendants' *Daubert* challenge of Keeys, Warner-Lambert already had pleaded guilty to multiple criminal violations relating to its marketing of Neurontin.[220] Indeed, the *Dellinger* court found that a jury could have concluded that Dellinger would not have been prescribed Neurontin as an off-label pain medication were it not for Warner-Lambert's illegal scheme.[221] Warner-Lambert's illegal actions—which included providing false and misleading information to doctors regarding Neurontin's off-label efficacy[222]—exposed Dellinger to dangerous side effects from an inappropriately prescribed drug, which is precisely the type of harm that the federal off-label promotion statutes are in part designed to protect patients against.

The defendants in *Dellinger* ostensibly made no attempt to demonstrate through expert evidence that Neurontin was not capable of causing pancreatitis or pneumonia. Thus, it is plain that the trial court based its decision on the view that Dellinger's expert had not established a sufficiently reliable basis for the conclusion that there had been a causal connection in Dellinger's case. In other words, though there remained an uncertainty whether Neurontin was capable of causing Dellinger's injuries and whether it did in fact cause Dellinger's injuries, the trial court did not appear to relax at all Dellinger's burden of resolving that uncertainty, even in light of Warner-Lambert's earlier admission of criminal misconduct. More generally, Warner-Lambert's underlying conduct did not even play a supporting role in the trial court's resolution of the admissibility question. The *Dellinger* court's analysis was thus an archetypal static bar approach.

Neurontin as the cause of Dellinger's maladies while "ruling out" the other medications that Dellinger continued to take. This is commonly referred to as "differential diagnosis" or "differential etiology." *See, e.g.*, Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262-63 (4th Cir. 1999) ("Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.").

[217] *Dellinger*, 2006 U.S. Dist. Lexis 96355, at *29.

[218] *Id.* at *31.

[219] *Id.* at *32, *34.

[220] *Id.* at *9.

[221] *Id.* at *23-*24.

[222] Department of Justice Release, *supra* note 208 ("[Warner-Lamber]'s agents . . . made false or misleading statements to health care professionals regarding Neurontin's efficacy and whether it had been approved by the FDA for the off-label uses.").

Now, to be sure, the criminal and civil penalties that Pfizer and Warner-Lambert paid as part of its settlement with the Department of Justice in 2005 might have represented a total disgorgement of the profits that the companies made through the illegal marketing scheme for Neurontin. Thus, it could be argued that tort liability for personal injuries that Neurontin might have caused to patients that would not have received the drug but for the illegal marketing schemes are not necessary to ensure optimal deterrence. However, this assumes that the government will obtain a high, if not perfect, level of detection and enforcement of similar illegal marketing schemes *and* that the public penalties will represent a full disgorgement. These assumptions are probably not empirically sound.[223]

To the extent that *Dellinger* is typical of the decision that one could expect going forward in similar cases, it skews a pharmaceutical company's decision whether to engage in illegal marketing schemes *ex ante*. Under *Dellinger*, where the causal connection between adverse events and the drug are plausible but not yet proven epidemiologically, the pharmaceutical company will not face liability for the personal injury damages its illegal marketing may cause. *Dellinger* virtually ensures that companies that engage in illegal marketing schemes will be able to avoid fully internalizing the costs of the personal injuries that their schemes cause. Thus, if a company faces only disgorgement of profits derived from the illegal scheme and not the externalized injuries suffered by patients, it will undertake the scheme so long as the probability of full disgorgement is less than one,[224] even though the social cost of its scheme exceeds its ill-gotten gains.[225]

It might be argued that whether *Dellinger* results in economically inefficient under-deterrence of violations of the off-label promotion statutes depends on whether those statutes themselves are economically efficient.[226] Alternatively, it might be argued that the knowing evasion of a legislatively-enacted statute (particularly one designed to ensure public safety) always or presumptively lacks social utility and that therefore over-deterrence of such knowing evasions should not be a concern.[227] Whichever view is taken, the important point is that a moving bar

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[223] *See* George S. Craft, Jr., Note, *Promoting Off-Label in Pursuit of Profit: An Examination of a Fraudulent Business Model*, 8 HOUS. J. HEALTH L. & POL'Y 103, 122 (2007) ("[T]he overall financial gains resulting from [the illegal marketing of Neurontin] . . . dwarf[ed] the $430 million global settlement.").

[224] *Cf.* RICHARD A. POSNER, ANTITRUST LAW: AN ECONOMIC PERSPECTIVE 223 (1976).

[225] In the case of Neurontin, the evidence was strong that the drug was responsible for at least *some* of the occurrences of pneumonia in patients using the drug. In fact, based on adverse event data from all Neurontin clinical trials, pneumonia already had been identified as a "frequent" adverse event experienced in patients taking the drug. *See* FDA Approved Labeling Text, February 2005, www.fda.gov/medWatch/SAFETY/2005/Feb_PI/Neurontin_PI.pdf (last visited Aug. 31, 2008).

[226] This is a topic that is beyond the scope of this Article.

[227] Warner-Lambert's violation of the off-label promotion statutes with regard to Neurontin was not only knowing, but it was also accompanied by the feeding of knowingly false and misleading information to doctors who prescribed the drugs to their patients. This type of statutory violation is less likely to serve any social utility. *Cf.* David A. Barker, *Environmental Crimes, Prosecutorial Discretion, and the Civil/Criminal Line*, 88 VA. L. REV. 1387, 1426-28 (2002) (arguing that criminal enforcement should "focus on the violator who

approach would have allowed the trial court in *Dellinger* to consider whether the illegal nature of the defendant's possibly injurious conduct militates in favor of a lower reliability bar for the plaintiff's causation expert because concerns with over-deterrence are reduced. That is, the trial court would have been allowed to determine that, in light of the nature of the defendant's possibly injurious conduct, erring on the side of potential excessive liability[228] made more sense than erring on the side of under-deterrence, and therefore Dellinger's expert would have been scrutinized a bit less at the admissibility stage.[229] In *Dellinger*, this might have made the difference between the plaintiff losing at summary judgment or, instead, surviving the defendant's *Daubert* challenge and getting to the jury.

C. Cases Involving Injuries Possibly Causally Connected to Consumer Products that Possess Questionable Social Utility

This subsection discusses the use of a moving bar approach to adjust the reliability bar downward and the likelihood that it will become more controversial and tricky: cases involving injuries possibly causally connected to consumer products that possess questionable social utility. In the context of pharmaceuticals, Professors Berger and Twerski have referred to such products as "lifestyle drugs," defined by the fact that they offer "little therapeutic value."[230]

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misleads the government and undermines the regulatory system through fraud, deception, or denial").

[228] By "excessive liability" the author means liability that exceeds the probabilistic harm that the defendant's conduct caused. For example, suppose that Neurontin caused a 20% increase in the occurrence of pneumonia among patients who were inappropriately prescribed the drug as a result of Warner-Lambert's illegal marketing scheme. Suppose further that every one of these patients sued Warner-Lambert and that juries ultimately found in favor of 50% of them. If this occurred, then Warner-Lambert's damages would be 2.5 times the probabilistic harm for which it was responsible.

[229] Adjusting the reliability bar downward in *Dellinger* seems intuitively correct from the perspective of fairness as well. Warner-Lambert's underlying conduct was not merely violative of the off-label promotion statutes; its conduct interfered with the relationship between Dellinger and his physician. Warner-Lambert's conduct was thus wrongful vis-à-vis Dellinger even *if* Neurontin was not the cause of Dellinger's physical injuries. When viewed in this way, Dellinger's personal injury lawsuit against Pfizer presented solely a question of the extent of the damages Dellinger suffered as a result of Warner-Lambert's illegal scheme. "The most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created." Bigelow v. RKO Radio Pictures, Inc., 327 U.S. 251, 265 (1946) (calling the principle "an ancient one").

[230] Berger & Twerski, *supra* note 130, at 268. I do not agree with Professor Berger's and Professor Twerski's characterization of certain products as "lifestyle drugs." For instance, their categorization of Bendectin as a lifestyle drug ignores the fact that morning sickness can often pose a serious risk to fetal health. *See* University of Illinois Medical Center: Health Library, Morning Sickness, http://uimc.discoveryhospital.com/main.php?id=2064 (last visited Aug. 31, 2008) ("Prolonged morning sickness can cause weight loss, dehydration, salt imbalances, and malnutrition. If these are not treated, they can lead to liver, kidney, heart, and brain damage to the mother and the fetus . . . . Severe morning sickness, or hyperemesis gravidarum, can cause low birth weight and fetal growth retardation. The blood flow to the placenta and fetus is also decreased[.] Less oxygen and nutrients are delivered to the baby. Low birth weight is often linked with poorer mental function and reduced overall health of the baby.").

One reason that a moving bar approach is likely to be more controversial and more tricky in this context is because it can be difficult to distinguish between consumer products with high social utility and those whose social utility is low or perhaps even non-existent. However, it seems obvious that certain products offer more potential benefits than others. For example, a vaccine that guards effectively against a serious virus seems clearly to possess greater social utility than an unregulated dietary supplement that claims to increase metabolism. Assume that the vaccine has a social value of $100 per inoculation, while the dietary supplement has a social value of $1 per person who takes it. If both products carry a one percent risk of causing a harm of $200, from an economic perspective the vaccine is net efficient ($98 net value per inoculation) while the dietary supplement is net inefficient (-$1 net value per person who takes it).

A regulator seeking economic efficiency would prohibit sales of the dietary supplement, but not the vaccine despite the fact that the two products pose the exact same risk of harm.[231] But, for a variety of reasons, oftentimes *ex ante* regulatory decisions do not achieve economic efficiency, and risk-causing behavior is sometimes unregulated or under-regulated.[232] This is where the tort system steps in.

The "all-or-nothing, more probable than not" standard hampers the tort system's ability to achieve optimal deterrence, however.[233] Comparing an important vaccine with an unregulated dietary supplement that offers minimal appreciable health benefits is again a useful exercise. Suppose that in a given population 100 people are expected to suffer from disease *X*, which causes each afflicted person a loss of $200. Suppose further that both a highly effective vaccine against H1N1 influenza and an objectively valueless (but creatively marketed), unregulated dietary supplement are both associated with a one percent increase in this background rate of disease *X*. Finally, suppose that for both the vaccine and the supplement the evidence of the causal connection to disease *X* is of the same quality and quantity.

In a lawsuit against either the manufacturer of the vaccine or the dietary supplement, the plaintiff suffering from disease *X* will have the burden to show that it is more probable than not that the defendant's product caused his disease. The plaintiff will need to introduce an expert willing to testify to this. For the plaintiff to withstand summary judgment, he or she will have to first withstand the defendant's *Daubert* challenge. The defendant's challenge will predictably argue that the expert's causation opinion is inherently unreliable given that the defendant's product is associated only with a paltry one percent increase in the background disease rate.

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[231] In a perfect functioning market, regulation would not be necessary. Instead, rational consumers would choose to avoid the dietary supplement. However, information asymmetries and other market failures militate against such a free market approach. *See generally* Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420 (1999). Even a perfect Pigovian tax requires consumers to accurately assess the utility of a product in order for the market to order consumer choices perfectly.

[232] *See* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 840 n.247 (1997) (reviewing briefly scholarship addressing causes of regulatory failure in the context of mass torts).

[233] *See generally* Rosenberg, *supra* note 109.

If the trial court excludes the plaintiff's expert, then the defendant will escape all liability even though there is a probabilistic harm of $2 associated with its product (.01 multiplied by $200). If, however, the trial court were to admit the evidence and allow the plaintiff to get to the jury, the defendant potentially could face liability of $200 for *each* of the 101 plaintiffs who took the defendant's product and subsequently were diagnosed with disease *X*. Even if juries found for the plaintiff only ten percent of the time, the manufacturers of the products would be faced with liability far exceeding the probabilistic harm of their products.

Under the "all-or-nothing" liability rule, a trial court deciding whether to exclude the evidence and dismiss the case on the one hand, or to admit the expert evidence and send the case to the jury on the other, has a choice: Err on the side of under-deterrence (exclude and dismiss despite probabilistic harm of $2) or err on the side of over-deterrence by exposing the defendant to potential "crushing liability" [234] of $200. There is simply no way around this.

The moving bar approach counsels that, in making its admissibility determination, the trial court should not decide between under- or over-deterrence in a vacuum. Rather, it should consider the nature of the defendant's potentially injurious conduct. In the disease *X* hypothetical described above, assuming that the defendant did not mislead consumers, violate any regulatory provisions, or otherwise act fraudulently in selling its product, the court should consider the social utility of the defendant's product. The court should lower the reliability bar in the lawsuit against the dietary supplement manufacturer and use a substantially higher bar in a lawsuit against the vaccine manufacturer. It is easy to see why: The probabilistic harm of the dietary supplement is $2 (.01 multiplied by $200), the social utility of the product is $0. Exposing the manufacturer of the dietary supplement to excessive tort liability does not result in inefficient over-deterrence.[235] With the vaccine, on the other hand, the product is clearly net socially efficient. Accordingly, ensuring that the manufacturer does not face excessive liability is a critical concern. Although precluding any tort recovery against the manufacturer of the vaccine would allow the manufacturer to avoid internalizing the probabilistic harm that its product causes ($2), the negative consequences of this are far outweighed by the negative consequences that excessive liability might cause, namely, the removal of the vaccine from the market. Moreover, if a court admitted the causation evidence against the vaccine manufacturer, it would send a signal to manufacturers of similar products with possible harmful side effects that they might also face crushing liability. Such manufacturers may withdraw their products from the market (or never bring them to market in the first place) despite the fact that the benefits outweigh the probabilistic harms associated with them.[236]

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[234] By "crushing liability," the author means liability that greatly exceeds the probabilistic harm caused by the conduct in question.

[235] Although plaintiffs would stand to gain a windfall, there is no concern with over-deterring the manufacturer of the dietary supplement because the product already is socially inefficient.

[236] This essentially is what happened with Bendectin, the drug at issue in *Daubert*, as well as the DPT vaccine. *See* W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 STAN. L. REV. 547, 584 (2000).

Few cases will be as straightforward as the stylized disease *X* hypothetical above. For example, if the dietary supplement created $5 in additional social value for each person who took it, then the product would be net socially efficient (assuming it was not associated with harms other than disease *X*, of course). What if the court is not sure of the supplement's per-use social value but thinks it is between $1 and $5—should the court err on the side of over-deterrence or under-deterrence? It is not the intent of this Article to provide answers to questions such as these. Rather, it is enough to point out that a court focused on economic deficiency might find it appropriate to lower the reliability bar in cases involving products with less social utility and raise it in cases involving products with greater social utility.

This is not what courts are doing under the *Daubert*/*Joiner* mode of analysis, however. The case *Linnen v. A.H. Robins Co., Inc.*,[237] involved a products liability suit against the manufacturer of diet pills containing fenfluramine-phentermine, ("fen-phen"). In *Linnen*, the decedent died of primary pulmonary hypertension (PPH) at age 30. The decedent had been diagnosed with PPH shortly after taking the defendant's diet pills for a period of three weeks.[238] The defendant argued in several pre-trial motions that there was no evidence linking the ingredients contained in its diet pills to PPH.[239]

The plaintiff, however, sought to introduce the testimony of Dr. Paul Wellman to prove causation.[240] Dr. Wellman was "a Professor of Psychology at Texas A & M University . . . who [had studied] the pharmacological and neurochemical bases of anorexia induced by appetite suppressant drugs. [He had] lectured and published on neurochemical and pharmacological mechanisms by which appetite suppressants reduce eating in animals."[241] Dr. Wellman testified that, in his expert opinion, the diet pills taken by the decedent had caused or contributed to the development of her PPH. He based his opinion on the following: First, clinical case studies collectively suggested an association between ingestion of fen-phen and PPH. Second, appetite suppressants with chemical structures similar to the defendant's diet pills have been shown to increase serotonin levels, and increased serotonin levels have been shown to cause or be "likely risk factors of" PPH.[242]

Dr. Wellman also "relie[d] on a variety of materials, including case reports [of adverse events], studies of other drugs that are pharmacologically related to phentermine, studies of the physiological effects of serotonin on animals, and an article he co-authored with Dr. Timothy Maher of the Massachusetts College of Pharmacy and Health Sciences" that was peer-reviewed and "published in the *International Journal of Obesity* in 1999."[243]

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[237] Linnen v. A.H. Robins Co., Inc., No. CIV. A. 97-2307, 2000 WL 16769 (Mass. Super. Dec. 14, 1999).

[238] *Id.* at *1.

[239] *Id.* at *6.

[240] *See generally id.*

[241] *Id.* at *1.

[242] *Id.* at *2.

[243] *Id.* at *2-*3.

Reviewing Dr. Wellman's expert opinion atomistically, the court held that it was unreliable and inadmissible. The court first concluded that Dr. Wellman's reliance on the adverse event case reports was not scientifically reliable:

> Case reports cannot be relied upon to establish association or causation between exposure and disease because they do not include control groups. The absence of a control group makes it impossible to determine whether the occurrence of the disease in a reported individual is attributable to the exposure or whether it would have occurred in the individual even absent the exposure.[244]

With regard to the scientific studies showing that fen-phen caused an increase in serotonin levels, the court noted that Dr. Wellman had relied on animal studies in forming this conclusion. These animal studies involved mice that were given doses of phentermine well above the dosage level given to humans.[245] Quoting the defendant's expert's critique of Dr. Wellman's opinion, the court stated, "animal studies have limited applicability to humans due to important differences between animals and humans, including differences in the bodies' reactions to a drug."[246] The court also rejected the reliability of Dr. Wellman's assumption that increased serotonin levels are a risk factor of PPH. The court agreed with the defendant's expert that it is improper to rely on theories about the biological mechanism by which a disease is triggered when no epidemiological studies support the hypothesis.[247]

Ultimately, the court held that Dr. Wellman's testimony was unreliable and inadmissible under *Daubert*. The fact that a peer-reviewed journal had earlier published a paper that Dr. Wellman authored proposing the existence of a link between PPH and fen-phen was not enough to save Dr. Wellman's opinion.[248] The court held that the lack of sufficient testing of Dr. Wellman's theory, its failure to obtain general acceptance of the theory in the scientific community, and Dr. Wellman's heavy reliance on animal studies was fatal to his opinion's admissibility. In a telling passage, the court summarized its criticism of Dr. Wellman's testimony by pointing to the differences between legal certainty and scientific certainty:

> Dr. Wellman acknowledges that he holds certain critical opinions in this case with less than a reasonable degree of scientific certainty. Those opinions include whether phentermine causes primary pulmonary hypertension, whether phentermine in combination with fenfluramine increases the risk of developing pulmonary hypertension, whether an increase in seratonin levels causes pulmonary hypertension, and whether phentermine alone increases seratonin levels.

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[244] *Id.* at *3 (quoting defendant's expert).

[245] *Id.* at *3-*4.

[246] *Id.* at *5 (quoting defendant's expert).

[247] *Id.* at *11.

[248] *See id.* at *5.

> The parties agree that an expert should be able to testify "to a reasonable degree of scientific certainty," but they dispute what constitutes that level of certainty. Plaintiffs urge that, because this is a civil trial, the standard for the admissibility of expert testimony should be the civil standard of proof, variously expressed by plaintiffs as a preponderance of the evidence, more likely than not, or, expressed numerically, 51% . . . .
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> . . . .
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> . . . When a witness testifies as to the principles and methodologies applicable to a particular scientific field—what might be termed pure science—that witness must testify with reasonable scientific certainty. Reliability under the rationale of . . . *Daubert* requires no less before potentially critical expert testimony may come before the jury . . . .
>
> . . . Although an expert's opinion as to the application of science to the facts of a case may be offered on the basis of probability, reasonableness and likelihood, the scientific principles or knowledge on which those opinions are based must be held with a reasonable degree of scientific certainty. That level of certainty, while it need not be absolute, must be greater than "more likely than not."[249]

The *Linnen* court's analysis is, again, an archetypal static bar approach. Nothing in the opinion remotely suggests that the court treated the height of the reliability bar as being any different than it would have been had the drug at issue been an FDA-approved drug designed to treat serious illness.[250] As suggested earlier in this subsection, this makes little sense from a deterrence perspective. If the tort system is intended to further "society's task [of selecting] those drugs with net beneficial health effects,"[251] then a court's reliability analysis should be altered to more resemble a regulatory risk assessment. This is what the moving bar approach tries to move toward.[252]

V. CONCLUSION: SOME OBJECTIONS TO THE MOVING BAR APPROACH

The author is under no illusions that the moving bar approach proposed is likely to raise a host of objections. In this concluding section, the author offers brief responses to a few of the objections that might be raised:

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[249] *Id.* at *12-*14.

[250] The defendant's product was neither FDA-approved nor designed as an obesity treatment. Most users of the product turned to it in order to lose "those last few pounds." *See* Michael D. Lemonick, *Dark Side of Diet Pills: Growing Reports of Serious Side Effects are Leading to Tough New Restrictions on Redux and Fen-Phen*, TIME, Sept. 22, 1997, at 81.

[251] Viscusi, *supra* note 236, at 585.

[252] While this article has focused on circumstances in which the moving bar approach would counsel a trial court to adjust the reliability bar downward, in some cases it will counsel a court to raise the reliability bar even *higher* than *Daubert* purports to set it.

Objection #1: The moving bar approach has no support in the plain language of Rule 702.

This objection is based upon a cramped reading of Rule 702. Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a [qualified witness] may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[253]

The rule's focus on the "sufficiency" of the facts or data, and the "reliability" of the witness's principles and methods and application thereof to the facts of the case do not foreclose a moving bar approach. Rule 702's key terms are "sufficient" and "reliable." These are relativistic terms,[254] and they have been treated as such in other legal contexts.[255]

The question, of course, is what factors to which the terms "sufficient" and "reliable" are relative. Traditionally, courts deciding whether to allow a plaintiff to get to the jury demanded less evidence of a causal connection between defendant's conduct and the plaintiff's injury in cases where the defendant's conduct was more reprehensible or otherwise warranted less protection from over-deterrence.[256] In other words, in determining whether evidence was "sufficient" to get the plaintiff to the jury, the trial court took into account the nature of the defendant's possibly injurious conduct. The moving bar approach simply incorporates this well known practice into the admissibility stage: A "reliable" opinion is one that, if accepted by jurors, would result in an outcome that could be deemed an "acceptable" outcome from the perspective of, *inter alia*, optimal deterrence.[257]

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[253] FED. R. EVID. 702.

[254] *See* Imwinkelried, *supra* note 28, at 269-70.

[255] For example, an anonymous witness's tip may be deemed sufficiently reliable to justify a *Terry* stop, but not sufficiently reliable to procure a search warrant. *See* Katherine Goldwasser, *After Abscam: An Examination of Congressional Proposals to Limit Targeting Discretion in Federal Undercover Investigations*, 36 EMORY L.J. 75, 134 (1987) ("[T]he test for reliability of informant information is more demanding under the probable cause standard than under the reasonable suspicion standard.").

[256] *See supra* text accompanying notes 20-21.

[257] I do think that Rule 702's plain language forecloses any approach to admissibility that would throw science out the window completely. For example, no matter how reprehensible the defendant's conduct, I do not think that Rule 702 would remotely contemplate letting a causation expert base her testimony on a Ouija board or a crystal ball. At a minimum, I think Rule 702 would require that an expert's methodology be consistent with the methodology that a regulatory risk-assessor would use, and that an expert should rely on the types of evidence upon which a regulatory risk-assessor would rely.

Objection #2: The moving bar approach inappropriately allows courts to engage in policymaking that should be reserved for regulatory agencies.

Concededly, the moving bar approach assumes not only that the courts have some role in regulating activities that pose risks, but also that their decision-making processes should be sensitive to substantive tort policies such as deterrence.[258] There is an ongoing debate whether regulatory policy-making is a task that should be left exclusively to legislatures and administrative agencies.[259] Entering this debate is beyond the scope of this Article, but there are a couple of points that are worth making in summary form.

First, commentators who object to courts engaging in regulatory policy-making argue that courts are neither electorally accountable nor particularly transparent.[260] However, most regulatory decisions are ultimately made by administrative agencies, as opposed to the legislature, and it is questionable whether administrative agencies are either significantly more democratically responsive or significantly more transparent than courts. "[T]he political pressures on an agency will not necessarily reflect society's preferences," which tends to dilute its democratic responsiveness.[261] Commentators have also recognized that agencies are uniquely vulnerable to interest group capture, which tends to negate the benefits of agency expertise.[262] Moreover, although a federal agency must allow "interested persons" the opportunity to comment on a proposed rule[263] and must base its final decision on "substantial evidence" and justify the decision in writing,[264] courts also allow (albeit in a more

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[258] Certain steps could be taken to minimize the degree that courts make policy under the moving bar approach. For example, if the nature of the defendant's conduct was simply treated as a "thumb on the scale" in an otherwise close case, then the moving bar approach would not give a court extreme policy-making authority.

[259] *See* Charles J. Doane, *Beyond Fear: Articulating a Modern Doctrine in Anticipatory Nuisance for Enjoining Improbable Threats of Catastrophic Harm*, 17 B.C. ENVTL. AFF. L. REV. 441, 447-48 (1990) ("Commentators and scholars have debated at some length on whether courts should play an active role in the regulation of modern technological risk . . . . These writers believe regulation of modern technological risks should be left largely to administrative agencies . . . . Meanwhile, those in favor of an increased judicial role question whether administrative agencies are sensitive enough to the public interest in regulating such risks. These writers also raise doubts . . . whether legislature[s] are capable of responding quickly enough to new sources of risk created by sudden accelerations in scientific knowledge.").

[260] *See, e.g.*, The Honorable Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L. J. 511, 515 (1989); Kenneth W. Starr, *Judicial Review in the Post*-Chevron *Era*, 3 YALE J. ON REG. 283, 306-09 (1986).

[261] *See, e.g.*, Jeffrey W. Stempel, *A More Complete Look at Complexity*, 40 ARIZ. L. REV. 781, 836 (1998).

[262] *See, e.g.*, C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629, 681 (2009) ("A shift from courts to agencies raises concerns about an agency's comparatively greater vulnerability to capture by regulated parties.").

[263] *See* 5 U.S.C. § 553(c) (2006).

[264] *See* 5 U.S.C. §§ 556, 557.

limited fashion) interested persons to participate in the judicial process through amici filings. Furthermore, the most important judicial decisions are accompanied by a detailed written opinion.

Second, the administrative rule-making process tends to take years. This is particularly true with respect to complex yet broadly important issues, such as whether a particular food or drug should be banned due to safety concerns. Consider the FDA's ban of ephedrine and ephedra-containing dietary supplements. The FDA's decision-making process began in June 1997. It was not until December 30, 2003 that the FDA issued its initial decision to ban ephedra, and it took until February 11, 2004 for the agency to issue its final rule.[265] During this nearly seven year rule-making process, ephedra manufacturers engaged in a "fierce lobbying" effort, and at least one commentator has described the FDA as having "been extraordinarily slow in instituting the ban . . . ."[266] Even if agencies do have an advantage over courts when it comes to regulatory expertise, this does not do much good if proposed regulations languish for years. To the extent that speed in reducing potentially harmful behavior is important, arguably the judicial system is superior to agency rule-making.

Third, while the threat of tort liability has the capacity to deter broadly, agency regulations have only the power to constrain narrowly. To return to the ephedra example, the FDA's ban on ephedra did not truly solve the public health problem that the agency was confronting. Rather, manufacturers simply began to create and sell new products with ephedra-like effects (and ephedra-like dangers) that were not captured by the ephedra ban.[267] The proposed moving bar approach would not be so easily evaded.

Finally, while the proposed moving bar approach provides courts a role in the regulatory decision-making process, it does not provide courts with anything close to the equivalent of an administrative agency's regulatory prerogative. Indeed, in those instances where it eases the burden of admissibility, the moving bar approach actually transfers power from the court to the *jury*.

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[265] *See* 69 Fed. Reg. 28,6788, 28,6789 (Feb. 11, 2004) ("The data do not indicate that [ephedra] products provide a health benefit sufficient to outweigh [the] risks [of stroke, heart attack, and death]."). Notably, a year after the FDA's decision, the Eleventh Circuit Court of Appeals reversed a jury's verdict in favor of a class of plaintiffs, who had sued Metabolife International, Inc. for injuries allegedly caused by their ingestion of Metabolife's ephedra-based weight loss supplements. *See* McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1236 (11th Cir. 2005). The Eleventh Circuit held that the district court had clearly erred in admitting the testimony of the plaintiffs' causation expert. *Id.* at 1238-59. The court's *Daubert* analysis reflected the type of static bar approach to reliability that I have criticized here. *See, e.g.*, *id.* at 1249 ("Obviously, [in applying *Daubert*] in a toxic tort case the court must focus on assessing causation, not on the cost-benefit analysis for restricting the sale and use of a drug.").

[266] Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 191 (2005) (disagreeing with the contention that "ephedra [is] an isolated example of problems inherent in FDA's laissez faire approach to supplements").

[267] Michael Sachs, Comment, *Ephedra and the Failure of Dietary Supplement Regulation*, 54 CATH. U. L. REV. 661, 694 (2005).

Objection #3: The moving bar approach will lead to an across-the-board watering down of the reliability standard.

This objection gets it backwards. A static bar approach is more likely to result in an across-the-board watering down of the reliability standard. It is plausible that courts confronted with sympathetic plaintiffs, such as those injured as a result of reprehensible conduct or by consumer products of questionable social utility, eventually will feel pressure to allow plaintiff's with shaky causation evidence to present their cases to the jury. Under a static bar approach, if courts begin to lower the reliability bar for these sympathetic plaintiffs, they will necessarily have suggested a lower bar in all cases.

Under a moving bar approach, courts would have case-specific, idiosyncratic reasons for their particular admissibility decisions. So, for example, in a case involving fen-phen, a court could admit an expert proffer based on animal studies without suggesting that reliance on animal studies would be sufficient in a case involving a valuable vaccine.

In addition, a moving bar approach will in some cases warrant an even *higher* reliability bar. Thus, the moving bar approach is not inherently "pro-plaintiff." Rather, the approach seeks to move the tort system toward optimal deterrence in spite of an "all-or-nothing" rule that is in inherent tension with optimal deterrence.

Objection #4: The moving bar approach will create windfalls for undeserving plaintiffs.

Under a moving bar approach, some indeterminate plaintiffs will get to the jury when they would not have under a static bar approach. And, some of these plaintiffs likely will receive compensation that exceeds the probabilistic harm caused by the defendant, which could be categorized as a windfall. However, it is important to note that surviving a *Daubert* challenge and summary judgment does not mean that the plaintiff will prevail at trial. Even in the most sympathetic of cases, plaintiffs with shaky causation evidence lose. For example, in the Bendectin litigation, where the causation evidence was always quite weak, nearly sixty percent of juries ruled in favor of Merrell Dow.[268] More recently, in the products liability litigation against Vioxx, which involved evidence of corporate wrong-doing on the part of Merck & Co., Inc., juries ruled in favor of plaintiffs in only fifty percent of cases.[269]

Admitting expert evidence will therefore merely force the parties to the bargaining table. Surviving a *Daubert* motion will obviously increase the settlement value of the plaintiff's case from what it was prior to the *Daubert* hearing value. But, the settlement value will still have to take into account the possibility that the evidence, while good enough to be admitted, will not be good enough to persuade a jury.[270] Ultimately, the valuation landscape may result in settlements that move

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[268] *See* MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 328 (1996).

[269] Frank M. McClellan, *The Vioxx Litigation: A Critical Look at Trial Tactics, the Tort System, and the Roles of Lawyers in Mass Tort Litigation*, 57 DEPAUL L. REV. 509, 509 (2008) (noting that Vioxx won nine of the fourteen cases that went to trial).

[270] *See* Nesson, *supra* note 126, at 536 (noting that, had Judge Weinstein "allowed the plaintiffs' experts to testify and the case to reach juries" in the Agent Orange litigation, "some plaintiffs would undoubtedly have lost; some may have won. The jury verdicts would have

toward an accurate reflection of the statistical probability of a causal connection between the defendant's conduct and the plaintiff's injuries.

In the end, the moving bar approach is an attempt to ease some of the existing tension between the substantive tort policy of deterrence and the manner in which modern courts tend to evaluate the reliability of expert evidence. This Article represents merely an opening in a renewed debate over how substantive tort policies can be integrated into the law of expert evidence.

begun to create a valuation landscape, and thus to provide a basis for negotiating settlements.").